REQUEST TO RECONSIDER DENIAL OF PETITION TO REQUIRE HEALTH AND ENVIRONMENTAL TESTING UNDER THE TOXIC SUBSTANCES CONTROL ACT ON CERTAIN PFAS MANUFACTURED BY CHEMOURS IN FAYETTEVILLE, NORTH CAROLINA

Executive Summary

Center for Environmental Health, Cape Fear River Watch, Clean Cape Fear, Democracy Green, the NC Black Alliance, and Toxic Free NC hereby request that the Environmental Protection Agency (EPA) reconsider and grant their October 14, 2020 petition under section 21 of the Toxic Substances Control Act (TSCA). Petitioners are non-profit public health, environmental and environmental justice groups in Eastern North Carolina. They represent communities impacted by contamination of the Cape Fear River basin by Per- and Polyfluoroalkyl Substances (PFAS) manufactured by The Chemours Company (Chemours) at its chemical production facility in Fayetteville, North Carolina. These communities are deeply concerned about the health consequences of their long-term exposure to PFAS.

The petition (Attachment A) requests that EPA address these concerns by requiring health and environmental effects testing on 54 PFAS produced and released into the environment by Chemours. It asks EPA to issue a rule or order under section 4 of TSCA compelling Chemours to fund and carry out this testing under the direction of a panel of independent scientists. As demonstrated in the petition, the 54 PFAS meet the criteria for testing in section 4(a) of TSCA.

The previous Administration denied the petition on January 7, 2021. As described below, the petition denial (Attachment B) was unsupportable under TSCA and contrary to the Biden EPA's commitment to protecting public health from the serious risks of PFAS pollution to communities. The denial deprives North Carolinians of the scientific data necessary to understand the long-term health consequences of PFAS exposure and refuses to hold Chemours responsible under TSCA for critical health and environmental studies that should have been performed decades ago.

EPA has broad power under TSCA to order manufacturers like Chemours to conduct testing to determine the safety of their products and processes. Congress amended TSCA in 2016 to strengthen EPA's tools for requiring chemical manufacturers to support testing of toxic chemicals they produce and release into the environment. Unfortunately, the Trump Administration refused to use this authority for PFAS and other chemicals. Now, however, the Biden EPA can reverse this history of inaction by immediately granting the petition and ordering Chemours to step up and devote its resources to understanding how its chemicals have affected people and the environment in North Carolina.

In its petition denial, the Trump EPA acknowledged its high level of concern about PFAS and did not deny that the 54 PFAS may pose serious health risks to the nearly 300,000 residents consuming

contaminated drinking water. It also offered no evidence that the 54 PFAS are *not* manufactured by Chemours. However, EPA rejected the petition because petitioners had not "proven" the absence of data for each of the 54 PFAS. This is a red herring. As the federal agency responsible for protecting people and the environment, it was EPA's job – not petitioners' – to determine how much information is available on these PFAS and whether it is sufficient to assess the health impacts of PFAS exposure. Since EPA did not do its job, petitioners have now conducted the comprehensive literature search that EPA should have performed. As described below, the results demonstrate what EPA should have already known: the limited data available are wholly inadequate to understand the risks of PFAS exposure to North Carolina residents and significantly more testing is needed.

EPA has the inherent authority to reconsider its denials of Section 21 petitions. The Agency has explained that: "Although TSCA does not expressly provide for requests to reconsider EPA denials of Section 21 petitions, 'the courts have uniformly concluded that administrative agencies possess inherent authority to reconsider their decisions, subject to certain limitations, regardless of whether they possess explicit statutory authority to do so.'" EPA Brief in *Trumpeter Swan Society v. Jackson*, 2014 WL 408986, at 23-24 (quoting *Tokyo Kikai Seisakusho, Ltd. v. United States*, 529 F.3d 1352, 1360 (Fed. Cir. 2008)). As the EPA has recognized, "the power to reconsider is inherent in the power to decide." *Id.* at 24 (quoting *Albertson v. FCC*, 182 F.2d 397, 399 (D.C. Cir. 1950)).

Overview of the Petition

PFAS have raised significant concern in the US and globally because of their persistence and potential to bio-accumulate, widespread presence in living organisms, products, and the environment, and demonstrated adverse health effects at low doses. EPA and many other authoritative bodies have noted the common characteristics of PFAS as a class. The Fayetteville chemical manufacturing facility, which is located on the Cape Fear River upstream of Wilmington, North Carolina, has long been a major producer and user of PFAS under the ownership of E. I. DuPont de Nemours & Company, Inc. (DuPont) and, since 2015, Chemours, a DuPont spinoff.

In the last few years, several of these PFAS have been identified in drinking water sources serving nearly 300,000 people in the Cape Fear watershed, in human blood and in environmental media, including air emissions, surface water, sediment, stormwater, groundwater and locally grown produce. Significant attention has been focused on "GenX" compounds. These chemicals have been produced as byproducts at the Fayetteville plant since the early 1980s. They were recently commercialized as a replacement for perfluorooctanoic acid (PFOA), a surfactant in the polymerization of fluoropolymers that was phased out in 2015 in response to serious health and environmental concerns. However, GenX compounds are only a small portion of the PFAS produced at the facility which have been shown to have actual or likely human exposure and presence in the environment. Petitioners have identified a total of 54 PFAS (not including legacy substances) that are attributable to the Chemours facility and have been detected in environmental media and/or people in the Cape Fear River watershed adjacent to and downstream of the plant site (shown in Figure 2).

Under a consent order between EPA and Chemours, GenX compounds have undergone some toxicological testing but, as EPA has recognized, available studies are incomplete. There is also some testing underway on a small number of other PFAS under a North Carolina consent order, but these studies are limited in scope. The petition showed that little or no health or environmental effects testing has been conducted on the remainder of the 54 PFAS and petitioners have now conducted a comprehensive literature search which confirms this conclusion. (Figure 1). Thus, for all 54 substances, there is an absence of sufficient data to determine risks to the large, exposed population within range of the Fayetteville facility and the surrounding ecosystem. This inability to determine the health impacts of their historical, ongoing and future PFAS exposure is a deep source of anxiety and concern to Cape Fear residents.

To date, EPA has failed to use its testing authorities under TSCA section 4 to fill the extensive data-gaps on PFAS. Congress included these tools in TSCA to assure that responsibility for developing information on the health and environmental impacts of chemicals is assigned to those businesses engaged in their production and commercial use. While the federal government and academic institutions have an important role to play in PFAS research, they should not and cannot shoulder the entire testing burden. A full understanding of this large and problematic chemical class will be impossible unless industry contributes its sizable resources to determining their risks to human health and the environment. The goal of the petition is to compel EPA to use its TSCA testing authorities to assure that industry assumes this responsibility.

Leading authorities have recognized that, because of the similarities in persistence, mobility, and toxicity among PFAS, all members of the class have the potential to cause the same adverse effects as well-characterized compounds such as PFOA and perfluorooctane sulfonate (PFOS). Based on the known hazards of these analogues, untested PFAS with potential for exposure would meet the criteria for testing in section 4(a)(1)(A) of TSCA because they (1) "may present an unreasonable risk of injury" and (2) have "insufficient information and experience" to determine their effects on health or the environment. This conclusion would plainly apply to the 54 PFAS subject to the petition because of their similarities to other well-studied PFAS, evidence of actual or likely human exposure and lack of sufficient data for informed determinations of risk. *See* Figure 2. For all these substances, testing is "necessary" under section 4(a)(1)(A) of TSCA because there is no other scientifically sound and reliable method for determining their health and environmental effects.

The scope of testing proposed in the petition differs depending on whether compounds fall into Tier 1 (detected in human sera, food or drinking water) or Tier 2 (significant potential for human exposure based on detection in environmental media and other evidence).

The petition proposes the following testing program:

Experimental Animal Studies

- Compounds in both Tiers would undergo 28-day repeated dose rodent toxicology studies coupled with reproductive and developmental toxicity screening assays and immunotoxicity assays, examining critical PFAS endpoints including hormone disruption, liver and kidney damage, developmental and reproductive harm, changes in serum lipid levels, and immune system toxicity.

- These studies would also be conducted on three mixtures of PFAS representative of the groups of substances to which residents have been exposed through drinking water, human sera and other pathways.

- Multigeneration or extended one-generation and 2-year rodent carcinogenicity studies would be conducted on the 14 Tier 1 substances in recognition of the evidence of direct and substantial human exposure and the concerns for these endpoints demonstrated by other PFAS.

- Most studies would be carried out in two species (mice and rats) and by oral routes of administration, except inhalation would be used for volatile chemicals.

- Toxicokinetic studies would be conducted to characterize relationships between serum concentrations and dermal, oral and inhalation exposures in the test species, and to evaluate biological half-life and potential for bioaccumulation.

- Testing requirements would be based on EPA and OECD guidelines, with appropriate adjustments to reflect sensitive endpoints that have been reported for PFOA, PFOS, and GenX.

Human Studies

- A human health study for the Cape Fear watershed would be conducted using a similar study design to that used for the Parkersburg, WV PFOA (C8) study. The goal of the study would be to determine the relationship between exposure to the mixtures of PFAS that characterize current and historical exposure in the Cape Fear watershed and health outcomes among exposed populations.

- Testing would also be performed to determine human half-lives of the listed chemicals through longitudinal biomonitoring and exposure estimation in workers.

Ecological Effects/Fate and Transport and Physical-Chemical Properties Studies

- Testing would include basic ecological effects studies, similar to studies conducted on GenX.

- EPA would require development of analytical standards where not currently available, physical- chemical properties tests, and fate and transport studies in order to identify and predict exposures.

The petition proposes that, to maximize the credibility and objectivity of the data and key findings, EPA would contract with the National Academy of Sciences (NAS) to form an independent expert science

panel with responsibility for overseeing all aspects of the testing program. The public and Chemours would have the opportunity to submit nominations for membership on the panel.

Why the Petition Denial was Unjustified and Should be Reversed

The January 7, 2021 petition denial affirmed EPA's "high concern" about PFAS and did not dispute that all PFAS are of concern for serious health effects based on the properties of the class. Nor did EPA deny the 54 PFAS are manufactured by Chemours and that most of them have been detected in the environment, resulting in exposure by North Carolina residents and putting them at risk of harm. Thus, EPA effectively conceded that the 54 PFAS "may present an unreasonable risk of injury," as required to justify testing under TSCA section 4(a)(1)(A).

In denying the petition, EPA tried to shift the focus away from these fundamental public health considerations and instead to discredit the petition on grounds that were irrelevant, demonstrably incorrect or merely petty. EPA's effort to put the onus on petitioners for failing to "prove" the absence of data on each of the 54 PFAS was particularly troubling when it is EPA – as the agency charged with protecting health and the environment -- that has responsibility for implementing TSCA and should be knowledgeable about the availability of data on chemicals of high concern like PFAS.

Petitioners show below why these justifications for the petition denial are without merit and the petition should be granted.

EPA Justification 1:

> *"To understand EPA's reasons for denying the petitioners' requests, it is important to first review the details of EPA's ongoing actions involving PFAS. EPA is committed to supporting states, tribes, and local communities in addressing challenges with PFAS. As a part of this effort, EPA is already taking action to identify solutions to address PFAS in the environment."* (Denial at 8)

Response:

The bulk of the petition denial (pp. 8-18) consists of a lengthy summary of the EPA PFAS Action Plan and a detailed list of the various PFAS-related measures EPA has taken under the Plan and other programs. This self-serving litany of EPA accomplishments is irrelevant to the petition. These EPA actions do not speak to whether the 54 PFAS in the petition meet the criteria for testing in section 4 of TSCA and provide no basis for denying the petition. Moreover, the PFAS Action Plan falls far short of addressing the many concerns raised by the petitioners about the risks resulting from their exposure to PFAS released from the Chemours Fayetteville facility. The presence of PFAS in the environmental media and people remains widespread and significant. Meaningful restrictions on commercial uses of PFAS and their releases to drinking water, surface water, air and disposal sites are still not in place. Thus, EPA cannot credibly claim that its limited and ineffective actions to prevent PFAS exposure under the Action

Plan eliminate the need for data to understand the health impacts of PFAS on exposed, at-risk communities. In fact, the Action Plan acknowledges the lack of health and environmental effects data for most PFAS and the need for more research – considerations that reinforce the petition's goal of using section 4 of TSCA to require industry to fund studies to fill critical PFAS data gaps.

EPA Justification 2:

> *"EPA finds the petitioners have not provided the facts necessary for the Agency to determine for each of the 54 PFAS that existing information and experience are insufficient and testing of such substance or mixture with respect to such effects is necessary to develop such information."* (Denial at 19)

Response:

It is simply not credible to suggest that the petition should be denied because it failed to demonstrate "insufficient information and experience" to determine the health and environmental effects of the 54 PFAS. EPA and many other expert bodies agree that there are fundamental data gaps for nearly all PFAS. It would be surprising if the 54 PFAS were an exception and the petition in fact demonstrated the need for testing of these substances.

As underscored in EPA's own PFAS Action Plan, "[t]here are many PFAS of potential concern to the public that may be found in the environment. Most of these PFAS lack sufficient toxicity data to inform our understanding of the potential for adverse human or ecological effects." Reinforcing the absence of toxicological data, ATSDR's draft 2018 Toxicological Profile for PFAS identifies numerous critical gap gaps across the PFAS class.

Even for GenX, one of the most high-profile and well-studied PFAS, EPA has acknowledged the insufficiency of available data. For example, EPA's draft 2018 Toxicity Assessment for GenX chemicals highlights the need for additional carcinogenicity studies:

> "One study is available on evaluating carcinogenicity of HFPO dimer acid and its ammonium salt in rats (DuPont-18405-1238, 2013). In this study, liver and pancreatic tumors were noted at the highest doses tested. The available data for HFPO dimer acid ammonium salt suggest that mice might be more sensitive to exposure to these GenX chemicals than rats. Given the evidence that the liver is the target organ for toxicity and the primary organ for tumor development, there is a need for additional research using chronic duration exposures in mice."

The EPA draft GenX toxicity assessment also notes that "[n]o data are available to evaluate cancer risk via dermal or inhalation exposure." The Action Plan expresses a similar concern for PFAS generally: "[l]imited data exist on health effects associated with inhalation or dermal exposure to PFAS." The draft GenX assessment also notes that "[d]ata for the elucidation of differential susceptibility dependent on

life stage (e.g., developing fetus, women of reproductive age, or pregnant women) are not available." This is likewise a data-gap for nearly all PFAS.

The pervasive lack of data on PFAS is not limited to health effect endpoints. The PFAS Action Plan recognizes that "Information for many PFAS sources, fate and transport, and human and ecological exposure is sparse, both spatially and temporally." The Plan further emphasizes that "[e]cological toxicity information is also needed by stakeholders to inform risk assessment and management to protect ecosystems, animals, and plant resources they support, and ultimately the human benefits that stem from these resources, including, for example, the prevention of potential PFAS risks associated with consuming game animals and fish."

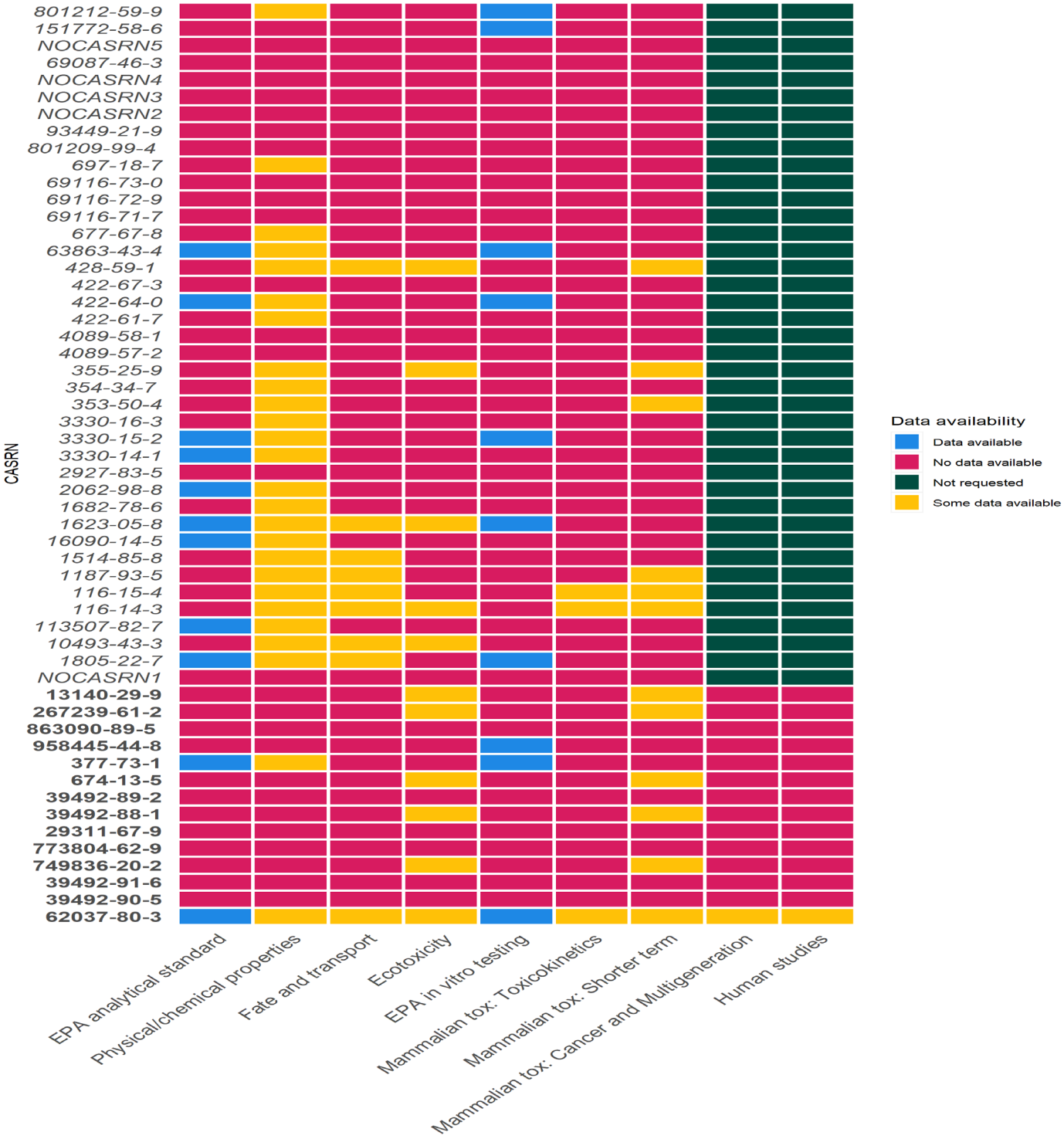
Petitioners did not present an exhaustive literature search in their petition but they reviewed the available data for the 54 PFAS and identified significant data gaps that would require additional testing to fill. As the petition indicates, some testing has been conducted or is underway on a small number of compounds but this limited testing fails to provide necessary data for the large majority of endpoints. No data are available for most the remaining PFAS. Thus, the petition properly concluded (pp. 1-2) that "for all 54 substances, there is an absence of sufficient data to determine risks to the large exposed population within range of the Fayetteville facility and the surrounding ecosystem."

The petition denial does not take issue with this broad conclusion. Instead, attempting to cast doubt on whether petitioners met their "burden of proof" under TSCA, EPA conducted "a cursory search of public literature and databases." (Denial, at 21). Not surprisingly, this search identified a small number of PFAS with some available data, as the petition itself had acknowledged. However, EPA made no effort to evaluate the adequacy of these data against the end-points and testing methodologies proposed for study in the petition. Thus, EPA failed to address the "sufficiency" of available information and experience for these PFAS under TSCA. It was EPA's job to perform this analysis and, had it been done, EPA would have immediately recognized that the limited data identified in its "cursory search" was inadequate to meet the information needs identified in the petition.

To eliminate any possible doubt about the insufficiency of available data and to compensate for EPA's inadequate analysis, petitioners' scientific consultants have now conducted a systematic and comprehensive literature search on the 54 PFAS. Physical-chemical properties, fate and transport studies and ecotoxicity studies were extracted from the EPA comptox dashboard and the ECHA database. Only experimental values were considered since limited information about the applicability domain of the predicting models is available for the PFAS chemicals. We enriched those properties found by screening the commercial chemical book database, including purchasable chemicals. For toxicity information, in addition to the ECHA database, we screened the EPA ChemView data-base to identify data submissions to EPA, and searched EPA's ToxValDB database. As previously noted, predicted values, such as predicted genotoxicity, were not extracted considering the lack of validation of these models for the PFAS chemicals. Finally, we conducted a literature review of PubMed for each chemical to identify any published toxicity studies that were not found elsewhere. An Excel spreadsheet

presenting the detailed results of the search is included in Attachment C and the findings are summarized in Figure 1 below:

Figure 1: Summary of available data for PFAS in the Chemours TSCA petition



As expected, Figure 1 shows that the 54 PFAS lack most or all of the studies proposed in our petition. For example, only GenX and tetrafluoroethylene have carcinogenicity studies (both positive) and in fact the carcinogenicity of tetrafluoroethylene was further confirmed in workers. None of the other 13 Tier 1 PFAS have carcinogenicity studies available in rodents or humans. Also, only GenX has a multigeneration reproduction and development study, which we requested for the 13 other Tier 1 PFAS. For the three shorter-term mammalian toxicity studies that are requested for all 54 PFAS—repeated dose, repro/developmental, and immune—similar studies are in progress or available for six PFAS under existing consent orders, although the targeted endpoints that we requested because they have been shown to be sensitive to PFAS are not generally included. Extremely limited short-term toxicity studies appear to be available for six additional PFAS; however, these did not assess endpoints now known to be important for PFAS. Similarly, large data gaps are shown in Figure 1 for ecotoxicology, fate and transport, and even basic physical-chemical properties of the chemicals. Even where data were reported, there were questions about whether they address critical PFAS-specific end-points using the methodologies proposed in the petition; if they did not, the data would be deemed inadequate and additional testing would be needed.

Not surprisingly, most of the reported toxicology data were for a small number of commercially significant compounds, such as Gen-X, tetrafluoroethylene and hexafluoropropylene. Even for these substances, however, there are still gaps in health effects and ecotoxicity information that would necessitate some further testing. Moreover, 41 of the 54 PFAS did not have any reported data for health and environmental effects, a disturbing finding since these substances have been detected in environmental and human exposure is anticipated.

Another troubling conclusion of the literature search is that, with one exception, no human epidemiological data were found. Similarly, only one substance (GenX) had data for immunological effects, an endpoint of high concern for PFAS as a class; studies for this endpoint are ongoing currently for 5 more compounds under North Carolina's Consent Order with Chemours. Also, no testing on mixtures for the endpoints identified in the petition was reported, even though exposure in drinking water and other environmental media is to multiple PFAS simultaneously.

Based on the literature search, there is no longer any reason to question the insufficiency of available information and experience on the health and ecological effects of the 54 PFAS. Thus, this prerequisite for requiring testing under section 4(a)(1)(A) of TSCA has been satisfied, eliminating the major ground cited by EPA for denying the petition.

EPA Justification 3:

> *"The petitioners do not demonstrate 'testing of such substance or mixture with respect to such effects is necessary to develop such information.' EPA finds that the petitioners failed to address ongoing testing and data collections for some of the 54 PFAS, thereby failing to set forth facts that are necessary to establish there is a need for the testing sought in the petition. This research may provide information that overlaps with testing the petitioners requested, which*

would render the information unnecessary under TSCA section 4(a)(1)(A)(i)(III). Testing, both planned and underway, on some of the 54 PFAS that the petitioners identify is described in this unit." (Denial at 23-24)

Response:

The petition denial's description of ongoing or planned EPA testing is confusing and incomplete. The test compounds are not identified and, in some cases, it is unclear who is conducting the testing. However, our scientific consultants' review indicates that only 9 of the 54 PFAS are undergoing testing by EPA. This research consists of *in vitro* assays, including high-throughput testing conducted by the EPA Office of Research and Development (ORD) to determine various markers of bioactivity that might signal the potential for *in vivo* effects. The health effects testing proposed in the petition consists of *in vivo* animal studies, epidemiological research and limited monitoring of workers. Thus, it is simply incorrect that the ongoing EPA "research may provide information that "overlaps with testing the petitioners requested, which would render the information unnecessary under TSCA section 4(a)(1)(A)(i)(III)."

No *in vitro* assays are proposed in the petition because non-animal test methods (New Approach Methods or NAMs) cannot at this time provide a scientifically sufficient understanding of the health and environmental effects of PFAS. Relying on these methods in lieu of *in vivo* animal or human studies would therefore be contrary to EPA's obligation under TSCA to require studies "necessary" to determine a substance's risks to health and the environment. The petition makes this point explicitly (p, 22): "toxicity testing in experimental animals [is] 'necessary' under TSCA because no alternative to animal testing is capable of developing reliable health effects information on individual PFAS at this time."

Concern about animal welfare has spurred interest in reducing reliance on animal testing systems. However, the goal of TSCA is protection of *human health* and animal studies have historically been essential in understanding the effects of chemicals on people. The 2016 TSCA amendments direct EPA to develop a strategy to reduce animal testing and encourage the development of NAMs as a substitute for traditional animal studies. However, the law is clear that, before NAMs can replace these tests, they must be shown to "provide information of equivalent or better scientific quality and relevance for assessing risks of injury to health or the environment of chemical substances or mixtures." 15 U.S.C. § 2603(h)(2)(A).

EPA's efforts to develop NAMs to predict the toxicity of chemicals have simply not progressed to the point where they satisfy this standard. For PFAS and many other chemical classes, the predictive value of NAMs cannot be validated without demonstrating strong correlations between NAMs and the results of animal and human testing across a broad cross-section of individual compounds. This work is not yet done, although the testing proposed in this petition would provide *in vivo* data needed to validate *in vitro* approaches for PFAS. While NAMs may be ready for widespread use for some simple and direct toxicity endpoints such as skin irritation, reliable methods for predicting complex systemic toxicities do not yet exist. NAMs are nowhere near ready to be used for assessing the effects associated with PFAS, such as developmental immunotoxicity, pancreatic tumors, and the effects on hormones, metabolism,

cholesterol, and glycogen storage in the fetal liver. Furthermore, as EPA has discovered, toxicokinetic parameters of PFAS are especially challenging to model without *in vivo* data. In sum, a PFAS testing program based on NAMs alone would fail to achieve TSCA section 4's goal of developing "sufficient information and experience" so that the effects of PFAS on health and the environment "can reasonably be determined or predicted."

Thus, studies of animals and humans, as proposed in the petition, are "necessary" under TSCA to obtain reliable and adequate information on the health effects of the 54 PFAS.

EPA Justification 4:

> *"The petitioners also call for an epidemiologic study consisting of 100,000 participants from communities exposed to PFAS-contaminated drinking water. A similar, multi-site health study is being implemented through the Centers for Disease Control and Prevention and ATSDR cooperative agreements. As ATSDR states, "[i]nformation learned from the multi-site study will help all communities in the U.S. with PFAS exposures, including those that were not part of the study." The petitioners mention this multi-site study but provide no analysis of overlap or what testing might be duplicative with what is proposed and thus might not be necessary, whether based on community characteristics, demographics, specific PFAS or mixture, or levels of exposure*."(Denial at 26-27)

Response:

The petition (p. 26) made a strong case for the need for human data as "an important way to identify health effects associated with the combined exposure to the many PFAS emitted from the Chemours facility, and to take into account toxicokinetics or susceptibilities that are unique to humans but not measured in rodent toxicity studies." The petition recognized the value of the ATSDR study but pointed out that the Cape Fear River basin in North Carolina was not among the seven areas selected for participation. The petition (p. 27) emphasized that:

> "The Cape Fear River is a source of drinking water for over 250,000 local residents downstream of Fayetteville and has been contaminated by multiple PFAS linked to the Chemours facility. Thus, there is an opportunity to examine whether health effects have occurred in this population due to drinking water exposure to a unique set of PFAS chemicals."

The uniqueness of PFAS exposure in North Carolina is a function of the very factors cited by EPA. Cape Fear communities have distinct demographics and health conditions, are exposed to a mix of PFAS uniquely associated with the Chemours facility and its operations, experience exposure by a specific set of drinking water and other pathways, and have had high long-term levels of exposure that likely differed in magnitude and duration from those in other communities. Thus, it is very unlikely that a North Carolina study would be "duplicative" of studies in other areas or that such studies would provide an understanding of health risks that is applicable to North Carolina residents.

Justification 5:

> *"For some of the 54 PFAS, only a degradant is detected in the Cape Fear River per the information provided by petitioners, not the parent chemical for which the petitioners have requested testing. The petitioners have not identified why it is necessary to test the parent chemicals and not the degradants actually detected in the Cape Fear River. For example, the petitioners do not demonstrate that testing of the parent chemical would identify effects relevant to the degradants."* (Denial at 27)

Response:

EPA does not identify the PFAS listed in the petition that it believes are "parent compounds" as opposed to "degradants" found in the environment and does not provide the data or other information that led it to this conclusion. We would need to review this information to understand EPA's concern. Generally, if EPA would prefer to require testing on "degradants," we would support this approach assuming the degradants can be identified with analytical precision and there is no technical or legal impediment to testing them.

Justification 6:

> *"The petitioners specifically identify and acknowledge that "5 of the 54 listed chemicals in this petition are also designated for testing in the Chemours North Carolina consent decree. These tests would not need to be replicated in response to this petition" (Ref. 1, pg. 30). EPA finds this avoidance of duplicative testing tacitly acknowledges that for these five PFAS, testing is not necessary to develop information on health or environmental effects. The petitioners' attempt to avoid duplicative testing as a result of the Chemours North Carolina consent decree, but no other duplicative testing, further emphasizes their failure to address readily available information concerning the other activities EPA has identified in this unit."* (Denial at 27)

Response:

This is an unfortunate distortion of our petition, which clearly states (p.3) that "Chemours would not be required to repeat studies already conducted or in progress." Our position has always been – and remains – that studies which provide the data called for in the petition would not need to be performed again, assuming that they reliably meet the scientific objectives identified in the petition. However, based on the extensive data-gaps demonstrated in our literature search (Figure 1), there is minimal overlap between the information needs described in the petition and existing studies. Thus, we expect that additional testing would be necessary on all 54 PFAS, including GenX and the five compounds subject to limited testing under the North Carolina consent order. In some cases, the knowledge objectives of the tests proposed in the petition may be met by supplementing or extending the studies being conducted under consent orders or other ongoing studies, for example by adding endpoints.

Justification 7:

> *"EPA is currently investigating ways to group similar PFAS by likeness into subcategories for purposes of research, data collection, hazard determinations, and other activities (Ref. 18) . . . The petitioners take the opposite approach, requesting testing on each of the 54 PFAS individually. The petitioners fail to address why a class-based approach is not appropriate, while also indirectly referring to the efforts to address PFAS as a class. . ."* (Denial at 27-28)

Response:

The studies proposed in the petition were selected to target well-documented concerns about PFAS that are the basis for drinking water guidelines for PFOA, PFOS, and GenX, and to avoid inefficient and unnecessary testing. While PFAS comprise a class of chemicals that appear to have similar characteristics and risk profiles, knowledge about relationships between structure and activity for this large, diverse, and dangerous class of chemicals is quite limited at this time. The goal of the petition is to determine real-world health effects from individual substances and mixtures present in the environment and contributing to human exposure. At this time, testing specific substances and mixtures is the best way to predict human health impacts with confidence. EPA's efforts to "group similar PFAS by likeness into subcategories" are worthwhile, but these investigations have not yet resulted in a peer-reviewed science-based framework for categorization to guide testing strategies. In fact, the testing proposed in this petition, when combined with suitable *in vitro* testing, is likely to be the basis for validating such approaches in the future. That said, if EPA has ideas on how representative substances within the 54 PFAS in the petition can be tested as surrogates for other substances, petitioners would be amenable to discussing these approaches after EPA has granted the petition and embarked on developing TSCA testing requirements for the 54 PFAS.

Justification 8:

> *"The petitioners also request that the National Academy of Sciences (NAS) oversee all aspects of the proposed testing program. EPA finds such an oversight arrangement is not within the scope of what a TSCA section 21 petitioner can request when seeking the initiation of a rule or the issuance of an order under TSCA section 4. Further, projects and studies must meet certain conditions for the NAS to accept private funding. . . EPA is not in a position to require NAS to oversee the testing requested by the petitioners, and the petitioners provide no administrative or organizational procedures for implementation."* (Denial at 29)

Response:

Petitioners proposed this approach because of the benefit of independent high-quality scientific advice in developing and carrying out the complex and important testing program proposed in the petition in a manner that is credible and fosters public confidence. The financial interests of corporate sponsors are known to bias the design of protocols and interpretation of results. Thus, effective safeguards for

scientific objectivity and integrity are critical for high-profile and cutting-edge research that impacts public health, such as testing of the 54 PFAS. There is nothing in TSCA that prevents EPA from seeking independent scientific oversight of section 4 testing programs and EPA peer review practices and policies strongly favor such an approach. While we see no reason why the National Academy of Sciences (NAS) could not perform this function, other options are available if NAS declined to participate. One possibility would be the independent Science Advisory Committee on Chemicals (SACC) created by section 26 of TSCA to provide scientific advice on actions taken under the law.

Justification 9:

> *"[T]he petitioners do not set forth facts showing that for all 40 PFAS it ranks as Tier 2 substances, 'human exposure is probable based on detection in environmental media" or that "a strong inference of exposure can be drawn from their presence in surface water, stormwater, wastewater, sediment, groundwater, soil, private wells, and/or air emissions' . . . [F]or nine of these [PFAS], no other studies are provided for inclusion based on presence in environmental media . . . Three of these nine PFAS were not directly detected in the two studies. Further, for some of these nine PFAS, only degradant products were detected in the Cape Fear River . . .* **"** (Denial at 29-20)

Response:

EPA does not identify the nine PFAS that it claims were not detected in the environment or the two studies it references. As noted above, it has also provided no information to demonstrate that six of these PFAS are parent compounds and not degradants.

In fact, EPA seems unaware that the Excel spreadsheet attached to the petition relies on 19 separate sources to establish that the 54 PFAS have either been found in environment media or are anticipated to have environmental releases and human exposure. For many of the PFAS, multiple sources are cited. The sources include not only three peer reviewed articles measuring PFAS in drinking and surface water and human blood but reports from the Food and Drug Administration and public utilities sourcing drinking water from the Cape Fear River. Petitioners also rely on monitoring conducted by Chemours under the North Carolina consent order which detected numerous PFAS in process streams, wastewater and other sources of discharges and emissions. In the aggregate, this evidence provides compelling documentation of the widespread environmental contamination stemming from the Chemours and DuPont operations and the extensive human exposure that occurred as a result.

Justification 10:

> *"The testing program the petitioners request would require testing on vertebrates. . . . the petition has not provided sufficient facts for EPA to consider reasonably available existing information and encourage and facilitate the use of test methods that reduce or replace the use of vertebrates [and] group chemical substances as appropriate to reduce the use of vertebrates . . . "* (Denial at 30-31)

Response:

As EPA notes, section 4(h)(1) of TSCA requires EPA to reduce testing on vertebrates "to the extent practicable, scientifically justified and consistent with the policies of this title." As discussed above and in the petition, as applied to PFAS, alternatives to animal studies are not sufficiently validated and developed to "provide information of equivalent or better scientific quality and relevance for assessing risks of injury to health or the environment," as required in section 4(h)(2)(A). Thus, the studies on vertebrates proposed in the petition are appropriate and justified under TSCA.

Conclusion

EPA's denial of the PFAS testing petition was unsupportable and denies petitioners answers to their serious concerns about the long-term effects of PFAS exposure. EPA should reconsider the petition denial and grant the petition.

As EPA moves forward, petitioners stand ready to work with EPA to address all scientific and legal concerns and provide further justification for the petition.

Respectfully submitted,

Center for Environmental Health
Thomas R. Fox
Senior Policy Advisor
tom@ceh.org

Cape Fear River Watch
Dana Sargent
Executive Director
dana@cfrw.us

Clean Cape Fear
Emily Donovan
Co-Founder
esdonovan@gmail.com

Democracy Green
Jovita Lee
lee.jovita93@gmail.com

Toxic Free NC
Alexis Luckey
Executive Director
alexis@toxicfreenc.org

The NC Black Alliance
La'Meshia Whittington
LaMeshia@ncblackalliance.org

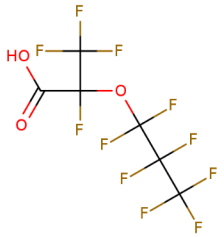
Robert M. Sussman
Sussman and Associates
3101 Garfield Street, NW
Washington DC 20008
202-716-0118
bobsussman1@comcast.net
Counsel for Petitioners

Ruthann Rudel, MS
Director of Research
Silent Spring Institute
320 Nevada Street
Newton MA 02460
617-332-4288 ext. 214
rudel@silentspring.org
Science Advisor

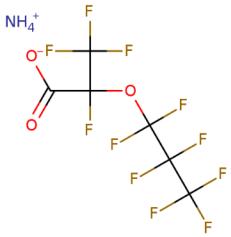
Drake Phelps
PhD Candidate
Department of Molecular Biomedical Sciences, College of Veterinary Medicine North Carolina State University
(434) 728-4293
drake_phelps@me.com
Science Advisor

FIGURE 2 – STRUCTURES OF PFAS IN PFAS TESTING PETITION

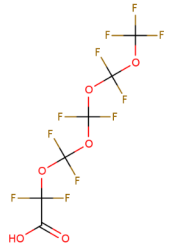
Figure 2a. Structures of tier 1 PFAS in the Chemours TSCA petition



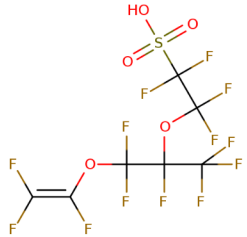
13252-13-6 | DTXSID70880215
Tier 1: Detected in drinking water, local food, and/or human blood



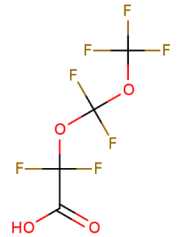
62037-80-3 | DTXSID40108559
Tier 1: Detected in drinking water, local food, and/or human blood



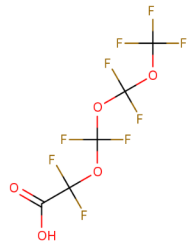
39492-90-5 | DTXSID90723993
Tier 1: Detected in drinking water, local food, and/or human blood



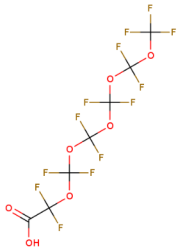
29311-67-9 | DTXSID30892354
Tier 1: Detected in drinking water, local food, and/or human blood



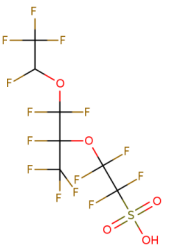
39492-88-1 | DTXSID50892351
Tier 1: Detected in drinking water, local food, and/or human blood



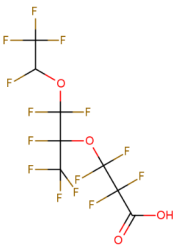
39492-89-2 | DTXSID20892348
Tier 1: Detected in drinking water, local food, and/or human blood



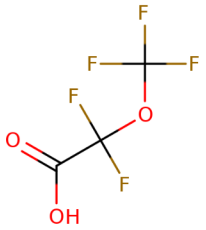
39492-91-6 | DTXSID50723994
Tier 1: Detected in drinking water, local food, and/or human blood



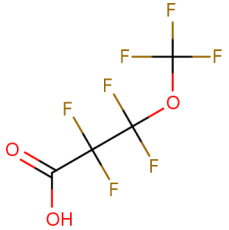
749836-20-2 | DTXSID10892352
Tier 1: Detected in drinking water, local food, and/or human blood



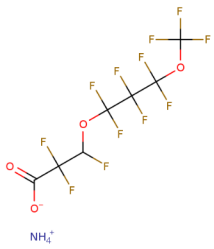
773804-62-9 | DTXSID60904459
Tier 1: Detected in drinking water, local food, and/or human blood



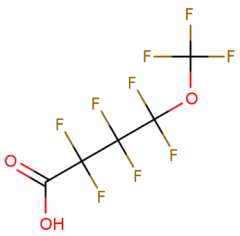
674-13-5 | DTXSID00408562
Tier 1: Detected in drinking water, local food, and/or human blood



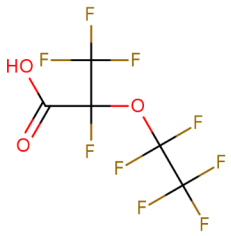
377-73-1 | DTXSID70191136
Tier 1: Detected in drinking water, local food, and/or human blood



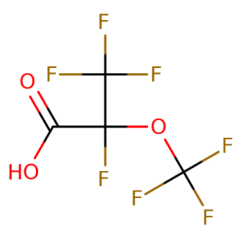
958445-44-8 | DTXSID00874026
Tier 1: Detected in drinking water, local food, and/or human blood



863090-89-5 | DTXSID60500450
Tier 1: Detected in drinking water, local food, and/or human blood

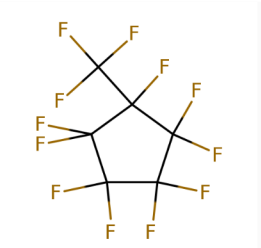


267239-61-2 | DTXSID60896486
Tier 1: Detected in drinking water, local food, and/or human blood

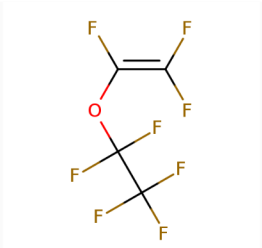


13140-29-9 | DTXSID80528474
Tier 1: Detected in drinking water, local food, and/or human blood

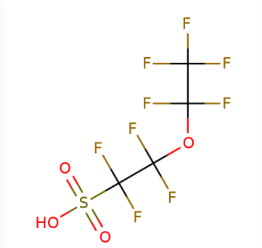
Figure 2b. Structures of tier 2 PFAS in the Chemours TSCA petition



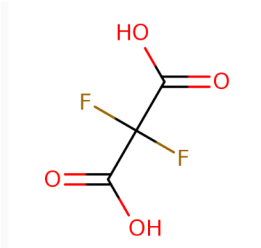
1805-22-7 | DTXSID7061982
Tier 2



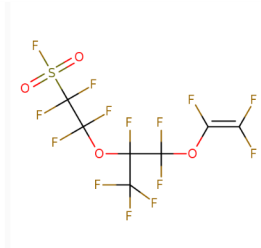
10493-43-3 | DTXSID1075305
Tier 2



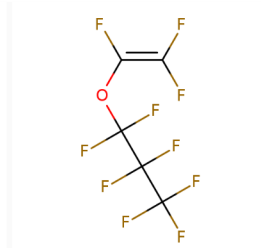
113507-82-7 | DTXSID50379814
Tier 2



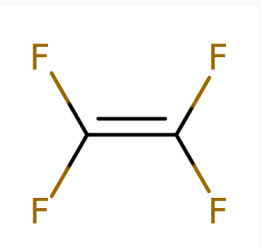
1514-85-8 | DTXSID60435930
Tier 2



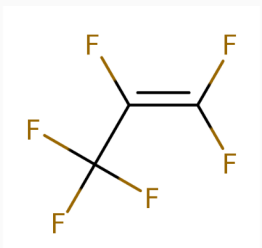
16090-14-5 | DTXSID3044596
Tier 2



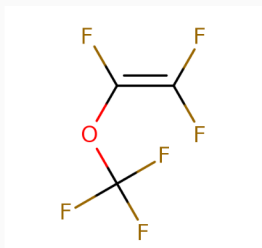
1623-05-8 | DTXSID0061826
Tier 2



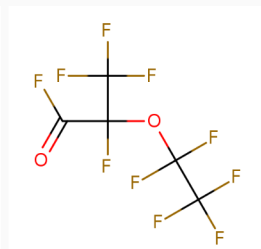
116-14-3 | DTXSID6021325
Tier 2



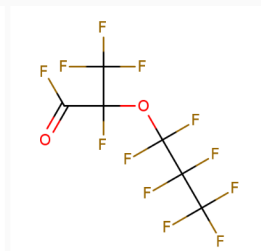
116-15-4 | DTXSID2026949
Tier 2



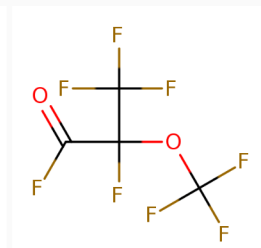
1187-93-5 | DTXSID3051599
Tier 2



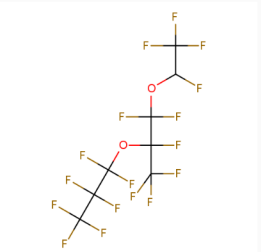
1682-78-6 | DTXSID50862736
Tier 2



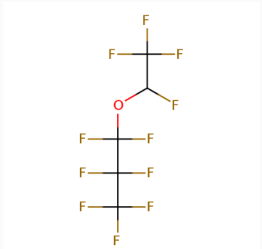
2062-98-8 | DTXSID60862823
Tier 2



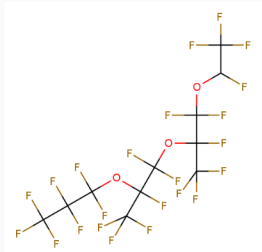
2927-83-5 | DTXSID80863059
Tier 2



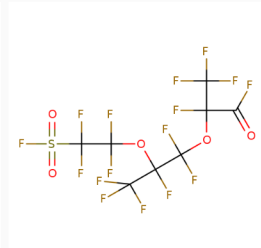
3330-14-1 | DTXSID50880192
Tier 2



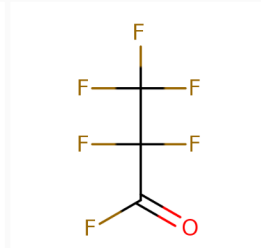
3330-15-2 | DTXSID8052017
Tier 2



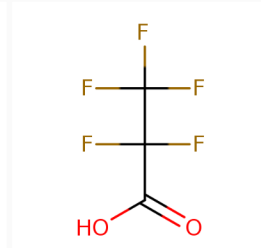
3330-16-3 | DTXSID10880193
Tier 2



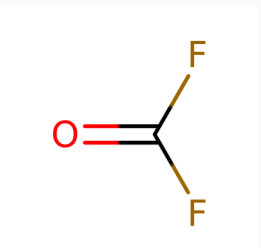
4089-58-1 | DTXSID40863318
Tier 2



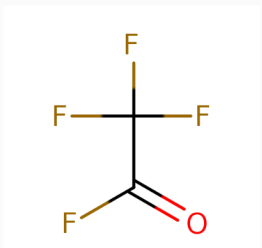
422-61-7 | DTXSID4059968
Tier 2



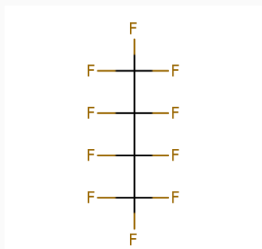
422-64-0 | DTXSID8059970
Tier 2



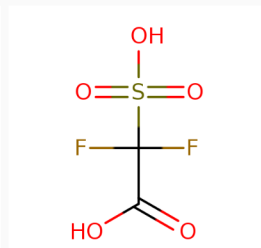
353-50-4 | DTXSID7059858
Tier 2



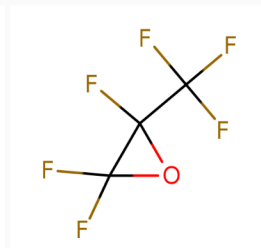
354-34-7 | DTXSID6059867
Tier 2



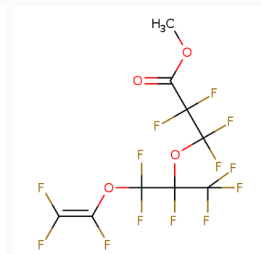
355-25-9 | DTXSID5059876
Tier 2



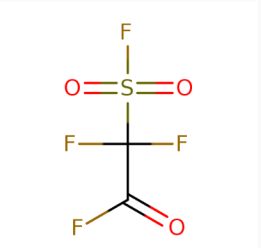
422-67-3 | DTXSID90349596
Tier 2



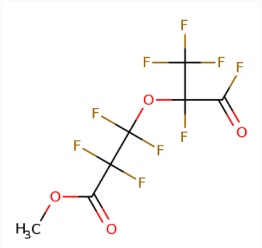
428-59-1 | DTXSID6029177
Tier 2



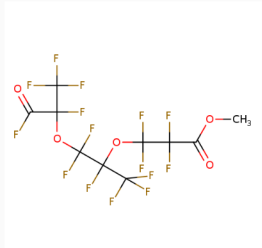
63863-43-4 | DTXSID8044969
Tier 2



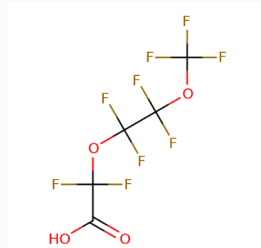
677-67-8 | DTXSID0060981
Tier 2



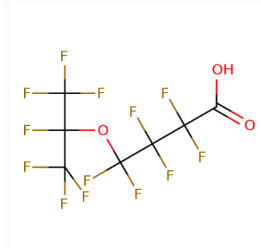
69116-72-9 | DTXSID70887648
Tier 2



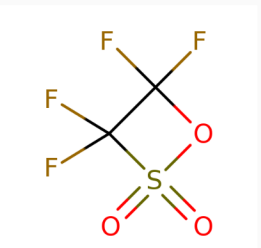
69116-73-0 | DTXSID90881284
Tier 2



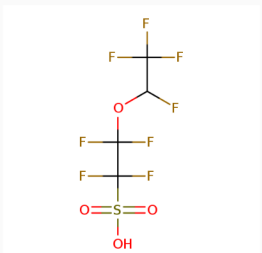
151772-58-6 | DTXSID30382063
Tier 2



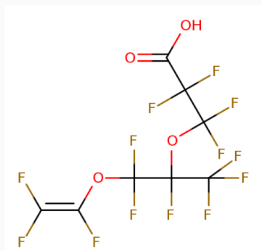
801212-59-9 | DTXSID60663110
Tier 2



697-18-7 | DTXSID7061017
Tier 2



801209-99-4 | DTXSID80904754
Tier 2



69087-46-3 | DTXSID00880940
Tier 2

ATTACHMENT A

PETITION TO REQUIRE HEALTH AND ENVIRONMENTAL TESTING UNDER THE TOXIC SUBSTANCES CONTROL ACT ON CERTAIN PFAS MANUFACTURED BY CHEMOURS IN FAYETTEVILLE, NORTH CAROLINA

Center for Environmental Health

Cape Fear River Watch

Clean Cape Fear

Democracy Green

Toxic Free NC

The NC Black Alliance

Petitioners

Robert M. Sussman
Sussman and Associates
3101 Garfield Street, NW
Washington DC 20008
202-716-0118
bobsussman1@comcast.net

Counsel to Petitioners

Ruthann Rudel. PhD
Director of Research
Silent Spring Institute
320 Nevada Street
Newton MA 02460
617-332-4288 ext. 214
www.silentspring.org

Drake Phelps
PhD Candidate
Department of Molecular Biomedical Sciences, College of Veterinary Medicine
North Carolina State University
(434) 728-4293
drake_phelps@me.com

Science Advisors to Petitioners

October 13, 2020

TABLE OF CONTENTS

ATTACHMENTS

TABLES

PETITION TO REQUIRE HEALTH AND ENVIRONMENTAL TESTING UNDER THE TOXIC SUBSTANCES CONTROL ACT ON CERTAIN PFAS MANUFACTURED BY CHEMOURS IN FAYETTEVILLE, NORTH CAROLINA

EXECUTIVE SUMMARY

This petition is submitted by Center for Environmental Health, Cape Fear River Watch, Clean Cape Fear, Democracy Green, the NC Black Alliance, and Toxic Free NC. Petitioners are non-profit public health, environmental and environmental justice groups based in North Carolina. Their petition is filed under Section 21 of the Toxic Substances Control Act (TSCA). It requests that that the Environmental Protection Agency (EPA) require health and environmental effects testing on 54 Per- and Polyfluoroalkyl Substances (PFAS) manufactured by The Chemours Company (Chemours) at its chemical production facility in Fayetteville, North Carolina. The petition seeks issuance of a rule or order under section 4 of TSCA compelling Chemours to fund and carry out this testing under the direction of a panel of independent scientists. As demonstrated in the petition, the 54 PFAS meet the criteria for testing in section 4(a) of TSCA.

PFAS have raised significant concern in the US and globally because of their persistence and potential to bio-accumulate, widespread presence in living organisms, products, and the environment, and demonstrated adverse health effects at low doses. EPA and many other authoritative bodies have noted the common characteristics of PFAS as a class. The Fayetteville chemical manufacturing facility, which is located on the Cape Fear River upstream of Wilmington, North Carolina, has long been a major producer and user of PFAS under the ownership of E. I. DuPont de Nemours & Company, Inc. (DuPont) and, since 2015, Chemours, a DuPont spinoff.

In the last few years, several of these PFAS have been identified in drinking water sources serving over a quarter of a million people in the Cape Fear watershed, in human blood and in environmental media, including air emissions, surface water, sediment, stormwater, groundwater and locally grown produce. Significant attention has been focused on "GenX" compounds. These chemicals have been produced as byproducts at the Fayetteville since the early 1980s. They were recently commercialized as a replacement for perfluorooctanoic acid (PFOA), a surfactant in the polymerization of fluoropolymers that was phased out in 2015 in response to serious health and environmental concerns. However, GenX compounds are only a portion of the PFAS produced at the facility which have been shown to have actual or likely human exposure and presence in the environment. Petitioners have identified a total of 54 PFAS (not including legacy substances) that are attributable to the Chemours facility and have been detected in environmental media and/or people in the Cape Fear River watershed adjacent to and downstream of the plant site. These 54 PFAS are identified in the attached Master Chemical List, with citations to the evidence demonstrating actual or likely exposure.

Under a consent order between EPA and Chemours, GenX compounds have undergone some toxicological testing but, as EPA has recognized, available studies are incomplete. There is also some testing underway on a small number of other PFAS under a North Carolina consent order, but these studies are limited in scope. No health or environmental effects testing has been conducted on the remainder of the 54 PFAS. Thus, for all 54 substances, there is an absence of sufficient data to determine risks to the large exposed population within range of the Fayetteville facility and the

surrounding ecosystem and to set risk reduction targets and other protective measures. For residents and their families, the inability to determine the health impacts of their historical, ongoing and future PFAS exposure is a deep source of anxiety and concern.

To date, EPA has failed to use its testing authorities under TSCA section 4 to fill the extensive data-gaps on PFAS. Congress included these tools in TSCA to assure that responsibility for developing information on the health and environmental impacts of chemicals is assigned to those businesses engaged in their production and commercial use. While the federal government and academic institutions have an important role to play in PFAS research, they should not and cannot shoulder the entire testing burden. A full understanding of this large and problematic chemical class will be impossible unless industry contributes its sizable resources to determining their risks to human health and the environment. The goal of this petition is to compel EPA to use its TSCA testing authorities to assure that industry assumes this responsibility.

Leading authorities have recognized that, because of the similarities in persistence, mobility, and toxicity among PFAS, all members of the class have the potential to cause the same adverse effects as well-characterized compounds such as PFOA and perfluorooctane sulfonate (PFOS). Based on the known hazards of these analogues, untested PFAS with potential for exposure would meet the criteria for testing in section 4(a)(1)(A) of TSCA because they (1) "may present an unreasonable risk of injury" and (2) have "insufficient information and experience" to determine their effects on health or the environment. Indeed, EPA took this very approach in reviewing GenX compounds under the related "new chemicals" provisions in section 5 of TSCA: it issued a consent order requiring testing based on findings that these compounds "may present an unreasonable risk" because of their similarities to PFOS and PFOA and "the information available to the Agency is insufficient to permit a reasoned evaluation of the[ir] human health and environmental effects."

The same conclusions are required under TSCA section 4(a)(1)(A) for the 54 PFAS in the Master Chemical List based on their similarities to other well-studied PFAS, evidence of actual or likely human exposure and lack of sufficient data for informed determinations of risk. For all these substances, testing is "necessary" under section 4(a)(1)(A) of TSCA because there is no other scientifically sound and reliable method for determining their health and environmental effects. Thus, this petition asks EPA to issue a test rule or order requiring Chemours to fund studies necessary to understand the likely health and environmental risks from past and ongoing exposure to the 54 PFAS.

Some of the 54 PFAS proposed for testing are intended commercial products while others are byproducts created during the manufacture of commercial products. The testing authority in section 4 of TSCA applies to both commercial products and byproducts from a commercial chemical manufacturing process. Thus, both types of PFAS are subject to section 4 testing requirements.

The scope of testing proposed in this petition would differ depending on whether compounds fall into Tier 1 (detection in human sera, food or drinking water) or Tier 2 (significant potential for human exposure based on detection in environmental media and other evidence).

The petition proposes the following testing program:

Experimental Animal Studies

- Compounds in both Tiers would undergo 28-day repeated dose rodent toxicology studies coupled with reproductive and developmental toxicity screening assays, examining critical PFAS endpoints including hormone disruption, liver and kidney damage, developmental and reproductive harm, changes in serum lipid levels, and immune system toxicity.

- These studies would also be conducted on three mixtures of PFAS representative of the groups of substances to which residents have been exposed through drinking water, human sera and other pathways.

- Multigeneration or extended one-generation and 2-year rodent carcinogenicity studies would be conducted on the 14 Tier 1 substances in recognition of the evidence of direct and substantial human exposure and the concerns for these endpoints demonstrated by other PFAS.

- Most studies would be carried out in two species (mice and rats) and by oral routes of administration, except inhalation would be used for volatile chemicals.

- Toxicokinetic studies would be conducted to characterize relationships between serum concentrations and dermal, oral and inhalation exposures in the test species, and to evaluate biological half-life and potential for bioaccumulation.

- Testing requirements would be based on EPA and OECD guidelines, with appropriate adjustments to reflect sensitive endpoints that have been reported for PFOA, PFOS, and GenX.

Human Studies

- A human health study for the Cape Fear watershed would be conducted using a similar study design to that used for the Parkersburg, WV PFOA (C8) study. The goal of the study would be to determine the relationship between exposure to the mixtures of PFAS that characterize current and historical exposure in the Cape Fear watershed and health outcomes among exposed populations.

- Testing would also be performed to determine human half-lives of the listed chemicals through longitudinal biomonitoring and exposure estimation in workers.

Ecological Effects/Fate and Transport and Physical-Chemical Properties Studies

- Testing would include ecological effects studies, similar to studies conducted on GenX.

- EPA would require development of analytical standards where not currently available, physical-chemical properties tests, and fate and transport studies in order to identify and predict exposures.

Avoidance of Duplication

- Chemours would not be required to repeat studies already conducted or in progress on GenX and the five substances subject to the North Carolina consent order but, because these studies are insufficient, additional studies on these PFAS would be conducted.

Independent Science Panel

- To maximize the credibility and objectivity of the data and key findings, EPA would contract with the National Academy of Sciences (NAS) to form an independent expert science panel with responsibility for overseeing all aspects of the testing program. The public and Chemours would have the opportunity to submit nominations for membership on the panel.

Chemours is taking steps to control environmental releases of PFAS under the consent order issued by the State of North Carolina in February 2019. These measures are critical to reduce human exposure to the 54 PFAS and should not be delayed while the testing proposed by this petition is underway. At the same time, it is important to recognize that Chemours' actions to reduce exposure do not eliminate the need for testing because PFAS exposure is continuing despite these actions and understanding the health impacts of both ongoing and historical exposure remains essential to protect exposed communities in the Cape Fear Watershed.

The body of this petition –

- describes the petitioning organizations and their concerns about PFAS exposure;
- reviews relevant TSCA provisions supporting the petition;
- provides an overview of health and environmental impacts of PFAS as a chemical class;
- identifies the 54 PFAS covered by the petition and the basis for their selection;
- describes the rationale for requiring testing of these substances under section 4 of TSCA;
- outlines the proposed framework for testing and specific studies to be required; and
- addresses how the test rule or order would be structured to maximize the relevance, quality and independence of the testing conducted.

I. CONCERNS OF THE PETITIONERS ABOUT PFAS EXPOSURE IN THE CAPE FEAR WATERSHED

The six petitioners are grassroots non-profit organizations committed to protecting North Carolina communities and ecosystems from the threat of toxic pollution. They are deeply concerned about the contamination of the Cape Fear River and resulting harm to human health from PFAS released into the environment by the Chemours Fayetteville chemical manufacturing facility.

More details on the goals and concerns of the petitioners are presented below.

- The *Center for Environmental Health* is a non-profit organization working to protect children and families from harmful chemicals in air, food, water and in everyday products. Its vision and mission are a world where everyone lives, works, learns and plays in a healthy environment; we protect people from toxic chemicals by working with communities, businesses, and the government to demand and support business practices that are safe for human health and the environment. CEH is headquartered in

Oakland, California and has offices in North Carolina, where it works closely with local groups on toxic pollution threats to North Carolina citizens.

- *Cape Fear River Watch* is a grassroots environmental nonprofit based in Wilmington, North Carolina whose mission is to protect and improve the water quality of the Cape Fear River Basin for all people through education, advocacy and action. Since our founding, over 25 years ago, we have worked on a wide variety of water quality issues – educating and organizing our community to take action, partnering with researchers, influencing decision makers, and holding polluters accountable. Since learning of the nearly four decades of PFAS contamination of our river, the drinking water supply for about 300,000 people, and a vital ecological and economical resource to our region, Cape Fear River Watch, in partnership with academia and the Southern Environmental Law Center, has worked to stop the source of pollution, understand and explain the impacts to human health and the ecosystem, and ensure that those responsible are held accountable.

- *Clean Cape Fear* is an all volunteer, grassroots community group based in the Wilmington, NC area. We're educators, environmentalists, doctors, faith leaders, scientists, veterans, and concerned residents all working together to hold Chemours/DuPont accountable for decades of pollution. We formed shortly after learning toxic chemicals linked to cancer and other serious health problems were detected in our finished tap water. These discharges and air emissions impact five counties with over 300,000 residents still drinking contaminated tap water downstream from Chemours and over 3,500+ well owners with contaminated groundwater near the Fayetteville, NC area. Chemours and DuPont did this for nearly 40 years until a local journalist alerted the public in 2017.

- *Democracy Green* is an organization created and run by native North Carolinians-of-color to address the systemic impacts burdening our most climate impacted and disenfranchised communities across North Carolina. We work in partnership with communities, groups and organizations across the historic U.S. South, in addition to areas hailing the descendants of U.S. chattel slavery and Indigenous sovereign nations. We have seen the horrific damage to communities wrought by *Per- and Polyfluoroalkyl Substances* on North Carolinians and we cannot stand idly by while the corporations responsible are not held accountable. Democracy Green stands against corporate polluters and the harmful impact of their pollutants and chemicals on frontline communities and low-wealth populations.

- The *NC Black Alliance* is working toward state-level systemic change by strengthening the network of elected officials representing communities of color throughout the state and collaborating with a progressive, grassroots networks on intersecting issues. We know, oftentimes the same communities impacted by climate disasters are the same

neighborhoods facing the direct impact of health disparities created by exposure to dangerous chemicals, such as *Per- and Polyfluoroalkyl Substances.* We believe all people have the right to clean air, clean water, access to health care, and a thriving economy.

- *Toxic Free NC* advances environmental health and justice in North Carolina by advocating for safe alternatives to harmful pesticides and chemicals. Founded in 1986, the organization has played a leading role in state-wide pesticide reform and has contributed to national efforts strengthening regulatory protections to protect vulnerable communities and the environment from petrochemical pollution. PFAS contamination is at the nexus of clean water concerns in North Carolina. Three years ago, we learned that GenX, an industrial PFAS chemical, was dumped for years into the Cape Fear waterway by the polluting Chemours company. While high levels of PFAS have been detected in drinking water across the state, the full health impact on the exposed residents of North Carolina is still unknown. Together with other organizations in North Carolina, Toxic Free NC advocates for regulatory solutions to prevent further PFAS discharge into our environment and cleanup the PFAS already present. We represent thousands of North Carolina residents whose drinking water has been contaminated and are deeply concerned about the consequences for their health.

II. KEY TSCA AUTHORITIES SUPPORTING THE PETITION

A. Testing Rules and Orders Under TSCA Section 4

As stated in section 2(b)(1), a core policy of TSCA is that "adequate information should be developed with respect to the effect of c hemical substances and mixtures on health and the environment and that the development of this information should be the responsibility of those who manufacture and those who process such chemical substances and mixtures." This policy is embodied in section 4 of TSCA, which provides EPA with broad authority to require industry to test its chemicals to determine their risks to human health and the environment. Recognizing the need for more testing to support chemical risk determinations, the 2016 TSCA amendments streamline section 4 by authorizing EPA to issue orders in addition to rules requiring development of data.

Of most relevance to this petition, section 4(a)(1)(A)(i) authorizes EPA to require testing where it determines that –

> the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, *may present an unreasonable risk of injury to health or the environment* (emphasis added).

Since the purpose of testing is to inform the assessment of a chemical's risks, the standard for a "may present" finding is a low one. In *Chemical Manufacturers Association v. U.S. Environmental Protection Agency,* 859 F.2d 977 (1988), the DC Circuit concluded that "[b]oth the wording and structure of TSCA reveal that Congress did not expect that EPA would have to document to a certainty the existence of an 'unreasonable risk' before it could require testing." It added that TSCA's legislative

history demonstrates that “the word ‘may" in section 4 was intended to focus the Agency's attention on chemical substances ‘about which there is a basis for concern, but about which there is inadequate information to reasonably predict or determine the effects of the substance or mixture on health or the environment.’"

The DC Circuit acknowledged that “Congress did not intend to authorize EPA to issue test rules on the basis of mere hunches” but stressed that EPA need not demonstrate that exposure or toxicity is “probable.” Instead, EPA may “rely on inferences in issuing a section 4 test rule, so long as all the evidence . . . indicates a more-than-theoretical probability of exposure.” Inferences can also support findings of potential toxicity; this can include toxicity data on chemical analogs since “Congress explicitly contemplated that EPA would base test rules on comparisons among structurally similar chemicals.” Indeed, EPA has repeatedly used Structure Activity Relationships (SAR) to support “may present” findings under both section 4 and the parallel new chemical review provisions of section 5.

In addition to a “may present” finding, section 4(a)(1)(A)(i) directs EPA to make two further determinations before requiring testing: (1) there is “insufficient information and experience” with which the chemical’s effects on health and the environment “can reasonably be determined or predicted”; and (2) testing is “necessary to develop such information.” The first determination will be justified whenever data either do not exist or are inadequate to support scientifically supportable conclusions about the chemical’s adverse effects. The second determination will be warranted where EPA concludes that testing is the only way to obtain sufficient information about these effects and that such information cannot be derived from other sources.

Once EPA makes these findings, it must require that testing be conducted “to develop information with respect to the health and environmental effects for which there is an insufficiency of information and experience” and which are “relevant to a determination” whether the substance “does or does not present an unreasonable risk to health and the environment.”

Under section 4(b)(2)(A), a broad range of studies may be required under test rules or orders. These may include studies to determine “carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects, and any other effect which may present an unreasonable risk of injury to health or the environment.” Studies to be conducted may include “epidemiologic studies, serial or tiered testing, in vitro tests, and whole animal tests.” The rule or order can also require development of information “for the assessment of exposure or exposure potential to humans or the environment.”

Under section 4(b)(3), testing rules or orders must place responsibility for developing the required data on the entities who manufacture and/or process the chemical to be tested. Section 4(b)(1) provides that the rule or order must prescribe the “protocols and methodologies” for conducting testing and procedures and deadlines for submitting interim and final test results. These requirements are enforceable under TSCA and non-compliance may give rise to civil and criminal penalties under section 16 and specific enforcement under section 17.

Testing under TSCA section 4 can be required on chemicals produced for intentional use or as byproducts during a commercial chemical manufacturing operation. EPA defines “byproduct” under TSCA as “any chemical substance or mixture produced without a separate commercial intent during

the manufacture, processing, use, or disposal of another chemical substance or mixture." 40 CFR § 712.3(a).

B. Recognition of Chemical Categories under TSCA 26(c)

Section 26(c)(1) of TSCA authorizes EPA to treat a group of chemical substances as a "category" under section 4 and other TSCA provisions. If the Agency designates chemicals as a "category," testing or other requirements prescribed by EPA would apply to each substance in the category. Under section 26(b)(2), "category" treatment is warranted if chemicals are "similar in molecular structure, in physical, chemical or biological properties, or in mode of entrance into the human body or into the environment" or "in some other way are suitable for classification as such for purposes of this Act."

The TSCA authority to address "categories" could be applied to all PFAS or to subgroups, such as the PFAS manufactured at the Chemours Fayetteville facility. Uniform testing or other requirements could then be applied to all PFAS in the category.

C. Citizens' Petitions under TSCA Section 21

This petition is filed under the authority of section 21 of TSCA, which enables "any person" to petition EPA to issue a rule or order requiring testing under section 4. The petition must demonstrate why the rule or order is "necessary." EPA must grant or deny the petition within 90 days. If EPA grants the petition, it must promptly begin the process to require testing by rule or order. If it denies the petition, EPA must publish a Federal Register notice explaining the reasons for the denial.

Where EPA denies the petition for a testing rule or order in whole or in part or fails to act in 90 days, the petitioner may file suit in a US District Court to challenge the petition denial or lack of action. The petitioner is entitled to a *de novo* proceeding on the merits of its petition, and the Court must direct EPA to initiate a proceeding to develop a test rule or order if it concludes, based on a preponderance of the evidence, that the chemical meets the criteria for requiring testing under section 4(a)(1)(A) of TSCA.

III. SERIOUS HEALTH AND ENVIRONMENTAL CONCERNS PRESENTED BY PFAS AS A CLASS

A. Production and Use

PFAS have a unique set of properties with an unusual ability to cause serious and widespread harm to public health and the environment. A defining feature of PFAS is their carbon-fluorine bonds, which impart high thermal stability and resistance to degradation. Because of their pronounced ability to repel oil and water, PFAS have been used in a variety of industries in the US and around the globe. They function as surfactants, friction reducers, and repellents of water, dirt, and oil. As a result, they are added to consumer products to impart nonstick (waterproof, greaseproof, and stainproof) and low-friction characteristics. Examples of products that contain or are coated with PFAS include carpets, glass, paper, clothing and other textiles, plastic articles, cookware, food packaging, electronics, and personal care products. PFAS also have many industrial applications, including as dispersants and emulsifiers, membranes, and firefighting foams.

EPA's 2019 PFAS Action Plan estimates that over 4,000 PFAS have been manufactured and used in a variety of industries and products worldwide since the 1940s and that over 1,000 PFAS are listed on the TSCA inventory (600 of which were reported for the Active Substance Inventory).[1-3, 38] These estimates do not reflect the large number of PFAS produced as byproducts and transformation products, which are not reportable for the TSCA Inventory but contribute to human exposure and environmental release.

The EPA Action Plan identifies numerous human exposure pathways for PFAS, including:[38]

- Drinking water from public water and private water systems, typically localized and associated with a release from a specific facility (e.g., manufacturer, processor, landfill, wastewater treatment, or facilities using PFAS-containing firefighting foams);
- Consumption of plants and meat from animals, including fish that have accumulated PFAS;
- Consumption of food that came into contact with PFAS-containing products (e.g., some microwaveable popcorn bags and grease-resistant papers);
- Use of, living with, or otherwise being exposed to commercial household products and indoor dust containing PFAS, including stain- and water-repellent textiles (including carpet, clothing and footwear), nonstick products (e.g., cookware), polishes, waxes, paints, and cleaning products;
- Employment in a workplace that produces or uses PFAS, including chemical production facilities or utilizing industries (e.g., chromium electroplating, electronics manufacturing, or oil recovery); and
- In utero fetal exposure and early childhood exposure via breastmilk from mothers exposed to PFAS.

B. Adverse Effects

PFAS are often called "forever" chemicals because they do not break down or degrade over time and therefore are highly persistent. Thus, they build up in the natural environment and in biological systems if they are bioaccumulative. These characteristics, combined with the high mobility of many PFAS, have resulted in their widespread distribution and pervasive presence both in environmental media and in people and wildlife around the globe, including many remote locations. Thus, PFAS have been detected in the blood of workers and the general population, with 99 percent of those sampled showing detectable levels of these compounds. This PFAS body burden is a function of multiple exposure pathways, including air emissions, food and water consumption, consumer products like carpet or clothing and house dust.[4] Because of their resistance to degradation, there is no known safe method of disposal of PFAS that would prevent build-up in the environment at the end of their useful lives.

In addition to their persistence, the threat posed by production and use of PFAS is amplified by their high mobility, especially in water. Their high water solubility and environmental persistence together make PFAS a ubiquitous pollutant of surface and groundwater. As a result, PFAS-contaminated drinking water is a widespread threat across the US; a growing number of drinking water suppliers have detected PFAS in source water or tap water, raising concerns about drinking water safety and resulting in use of costly treatment systems in numerous communities across the country.[5]

Animal studies demonstrate that PFAS are linked to many serious health effects, including cancer, hormone disruption, liver and kidney damage, developmental and reproductive harm, changes in serum lipid levels, and immunotoxicity, often at low doses. Human studies of populations with elevated blood levels of PFAS have shown associations with a variety of health conditions, including kidney and testicular cancer, elevated cholesterol, liver disease, decreased fertility, thyroid problems and changes in hormone levels and immune systems.[4] Moreover, concurrent exposure to multiple PFAS may have additive or synergistic effects.

C. Transition to Short-chain and Other Replacement Chemistries

Initially, health and environmental concerns about PFAS were focused on "long-chain" substances, consisting of perfluoroalkylcarboxylic acids (PFCA) and perfluoroalkanesulfonic acids (PFSA) with six or more fluorinated carbons. Within these chemical classes, PFOA and PFOS (along with their precursors and degradation products) received the greatest attention because of their commercial prominence and widespread detection in people and the environment. As scientific and regulatory concerns surfaced, 3M Corporation stopped producing PFOA and PFOS in the early 2000s, and DuPont and other producers agreed in 2006 to phase out PFOA and other PFCA compounds by 2015.[6]

The shift away from long-chain PFCA and PFSA was accompanied by the increased use of shorter-chain substances as substitutes in many historical PFAS applications. Prominent short-chain substitutes include perfluorobutanoic acid (PFBA), perfluorobutanesulfonic acid (PFBS), perfluorohexanoic acid (PFHxA), and GenX. There has also been substitution of long-chain per- and polyfluoroalkyl ether carboxylic acids (PFECAs) as well as per- and polyfluoroalkyl sulfonic acids (PFESAs). Although initially assumed to be less harmful, growing evidence indicates that short-chain PFAS, PFECAs, and PFESAs have characteristics similar to those of PFOS, PFOA and other long-chain PFAS. In its PFAS Action Plan EPA recognized that, although the "toxicities of short-chain PFAS have generally been less thoroughly studied," they are "as persistent in the environment as their longer-chain analogues and are highly mobile in soil and water."[7] Moreover, as production has increased, short-chain PFAS, PFECAs, and PFESAs have been found in human sera and the environment and the limited testing conducted has demonstrated health effects common to long-chain PFAS, including hepatic and renal effects, suppressed immune function and changes to liver weight, serum cholesterol, and thyroid hormones.[3,4]

IV. PFAS PRODUCTION AT THE CHEMOURS FAYETTEVILLE FACILITY AND CONTAMINATION OF THE CAPE FEAR WATERSHED

The Chemours plant is located on a 2,150-acre site in a rural area south of Fayetteville, North Carolina, adjacent to the west bank of the Cape Fear River. The river continues for over 110 km to the City of Wilmington and then broadens into an estuary that ultimately flows into the Atlantic Ocean. Residents of Wilmington and other population centers downstream from the facility use the river as a source of drinking water. The facility was built and operated by DuPont and started producing fluoropolymers in 1971. In 2015, DuPont spun off its performance chemicals business to Chemours, a newly created company which then acquired the Fayetteville plant and other former DuPont facilities.

The plant is a major producer and user of PFAS. Its PFAS-based product lines are Fluoromonomers, Fluorinated Vinyl Ethers and Nafion® Polymers, which are used as membranes in fuel cells and chlorine production.[8] The mix of precursors, byproducts, degradation products and commercial substances associated with these product lines is complex and not well-understood but likely involves hundreds if

not thousands of individual PFAS, many of which have chemical structures that are as yet unidentified. A chart describing the major chemical manufacturing streams at the facility is provided in Attachment 1.

The Fayetteville facility began producing PFOA in 2001 following the 3M phaseout, but as concerns about PFOA mounted, efforts were undertaken to find a shorter-chain PFAS that could replace PFOA as a processing aid (surfactant) in manufacture of Teflon fluoropolymers. The result was commercialization of a group of compounds with the GenX tradename. According to the North Carolina consent order,[23] these chemicals consist of the C3 Dimer Acid (also known as Hexafluoropropylene Oxide (HFPO) Dimer Acid), CAS No. 13252-13-6; the C3 Dimer Acid Fluoride (also known as HFPO Dimer Acid Fluoride), CAS No. 2062-98-8; and the C3 Dimer Acid Ammonium Salt (also known as HFPO Dimer Acid Ammonium Salt), CAS No. 62037-80-3. (HFPO is also a building block chemical for several other PFAS-based products manufactured at the facility and is sold commercially).

GenX compounds have been produced as byproducts of the Nafion product line since 1980.[8] However, anticipating their introduction as a commercial product, in 2008, DuPont filed two premanufacture notices (PMNs) for these chemicals under section 5 of TSCA (P-08-0508 and P-08-0509). Based on similarities between GenX and PFOS and PFOA, EPA and DuPont entered into a consent order[9] in January 2009 requiring toxicological testing of GenX and limitations on production, worker exposure and environmental release. With the consent order in place, DuPont began commercial production of GenX at the Fayetteville plant, touting it as a "sustainable replacement" for PFOA. GenX produced in North Carolina was supplied to the Dupont fluoropolymer manufacturing facility in Parkersburg, West Virginia, a site where prior use of PFOA had previously resulted in widespread contamination of drinking water.

The 2009 EPA consent order restricted discharges of wastewater containing GenX compounds but this restriction did not apply when these chemicals were produced as byproducts in other plant operations. GenX chemicals were detected in the Cape Fear River and its tributaries in the summer of 2012[10] and follow-up sampling in 2013 identified significant levels of GenX in source water at drinking water treatment plants using surface water from the river.[11] Subsequent sampling showed that conventional and advanced water treatment processes did not measurably reduce GenX concentrations in finished water. GenX has also been detected in tap water in Louisville, Kentucky,[12] in drinking water near Chemours plant in Parkersburg, West Virginia[13], and near a Chemours production facility in the Netherlands.[14] GenX contamination has spread globally, with these compounds now being detected in the Arctic Ocean.[15] GenX was detected in fish in the Cape Fear Drainage Basin as early as 2007.[16]

Despite the attention it has received, GenX is only one of the PFAS that have been detected in environmental media in the Cape Fear watershed and may not be the contaminant of greatest concern. During the initial work of Strynar et al. and Sun et al., nine other PFAS were identified in the Cape Fear River and drinking water downstream of the Fayetteville plant.[17] In some cases, concentrations of these PFAS were above those of GenX. In further sampling of the river downstream of the plant, McCord et al. (2019) found 37 unique PFAS molecules.[18] Based on their structures, the detected PFAS were grouped into three categories corresponding to distinct segments of the plant's operations (fluoromonomer, Nafion membrane and fluorinated vinyl ether production). Several of these compounds were also detected in the blood of residents of the Cape Fear region, confirming human exposure.[19] Sampling in the Cape fear River indicated that total PFAS concentrations (all substances combined) were 130,000 parts per trillion (ppt).[20]

As concern increased about surface water and drinking water contamination, monitoring of other environmental media for the presence of PFAS produced at the Fayetteville plant was initiated. As determined in Chemours' own compliance testing under the North Carolina consent order, several additional PFAS associated with the Fayetteville Works facility have been detected in private wells[21], wastewater[22], stormwater[22], sediment[23,24], groundwater[23], soil[23], air emissions[25], and local produce[26], including a large number of compounds of uncertain chemical composition.

The 2019 consent order between Chemours and the North Carolina Department of Environmental Quality (DEQ) [27] requires controls on wastewater discharges and air emissions of PFAS, directs Chemours to identify constituents of wastewater and process streams and to conduct environmental monitoring, provides for groundwater remediation, and requires health and environmental effects testing of five PFAS.[27] Sampling of drinking water systems and private wells since the order was issued indicates the continuing presence of GenX and several other PFAS.[28,29]

V. SELECTION OF PFAS FOR HEALTH AND ENVIRONMENTAL EFFECTS TESTING

As described above, multiple PFAS linked to Chemours operations have been found in human blood, drinking water and/or other environmental media downstream of the Fayetteville plant. These chemicals warrant health and environmental effects studies because data on their effects are insufficient or unavailable and they may present unreasonable risks because of the combination of potential toxicity and exposure. As a foundation for testing to fill these data gaps, petitioners have developed a list of 54 PFAS produced at the plant for which there is evidence of known or anticipated human exposure as demonstrated by available data on their presence in human sera, drinking water, surface water, air emissions, rainwater, private wells, groundwater and produce. The list was divided into Tier 1 substances (for which there is known human exposure based on detection in blood, food or drinking water) and Tier 2 substances (for which human exposure is probable based on detection in environmental media). The detailed justification for assigning substances to these Tiers is provided in two related spreadsheets in Attachment 2, the Chemours PFAS Master Testing List[2,5,10,11,17-26,28-38]. The 54 testing candidates are summarized below in Table 1:

TABLE 1: LIST OF 54 CHEMICALS FOR TSCA PETITION

#	Abbreviation	Name	DTXSID	Tier
1	HFPO-DA (GenX)	perfluoro-2-propoxypropanoic acid (related to GenX: ammonium perfluoro-2-methyl-3-oxahexanoate 62037-80-3 | DTXSID40108559)	DTXSID70880215	1
2	PFO4DA	perfluoro(3,5,7,9-tetraoxadecanoic) acid	DTXSID90723993	1
3	PFO5DoDA (aka TAF)	perfluoro(3,5,7,9,11-pentoxadodecanoic) acid	DTXSID50723994	1

4	Nafion byproduct 2	2-[1-[difluoro(1,2,2,2-tetrafluoroethoxy)methyl]-1,2,2,2-tetrafluoroethoxy]-1,1,2,2-tetrafluoroethanesulfonic acid	DTXSID10892352	1
5	Hydro-EVE acid	3-[1-[difluoro(1,2,2,2-tetrafluoroethoxy)methyl-1,2,2,2-tetrafluoroethoxy]-2,2,3,3-tetrafluoro-propanoic acid	DTXSID60904459	1
6	Nafion byproduct 1	1,1,2,2-tetrafluoro-2-({1,1,1,2,3,3-hexafluoro-3-[(1,2,2-trifluoroethenyl)oxy]propan-2-yl}oxy)ethane-1-sulfonic acid	DTXSID30892354	1
7	PFO2HxA	perfluoro(3,5-dioxahexanoic) acid	DTXSID50892351	1
8	PFO3OA	perfluoro(3,5,7-trioxaoctanoic) acid	DTXSID20892348	1
9	PFMOAA	perfluoro-2-methoxyacetic acid	DTXSID00408562	1
10	PFMOPrA	perfluoromethoxypropionic acid	DTXSID70191136	1
11	NaDONA	sodium dodecafluoro-3H- 4,8-dioxanonanoate	DTXSID00874026	1
12	PFMOBA	perfluoro(4-methoxybutanoic) acid	DTXSID60500450	1
13	PEPA	perfluoroethoxypropyl carboxylic acid	DTXSID60896486	1
14	PMPA	perfluoromethoxypropyl carboxylic acid	DTXSID80528474	1
15	N1AF	N1AF	-	2
16	PMCP	perfluoromethylcyclopentane	DTXSID7061982	2
17	PEVE	pentafluoroethyl trifluorovinyl ether	DTXSID1075305	2
18	PES	perfluoro(2-ethoxyethane)sulphonic acid	DTXSID50379814	2
19	TFE	tetrafluoroethylene	DTXSID6021325	2
20	HFP	hexafluoropropylene	DTXSID2026949	2

21	PMVE	perflouromethylperfluorovinyl ether	DTXSID3051599	2
22	(was MMF)	difluoropropanedioicacid	DTXSID60435930	2
23	PSEPVE	perfluoro (4-methyl-3, 6- dioxaoct-7-ene)sulfonyl fluoride	DTXSID3044596	2
24	PPVE	heptafluoropropyl trifluorovinyl ether	DTXSID0061826	2
25	PEPF	2,3,3,3-tetrafluoro-2-(1,1,2,2,2-pentafluoroethoxy)propanoyl fluoride (aka perfluoroethoxypropionyl fluoride)	DTXSID50862736	2
26	HFPO-DAF	2,3,3,3-tetrafluoro-2-(1,1,2,2,3,3,3-heptafluoropropoxy)propanoyl fluoride	DTXSID60862823	2
27	PMPF	2,3,3,3-tetrafluoro-2-(trifluoromethoxy)propanoyl fluoride (aka perfluoromethoxypropionyl fluoride)	DTXSID80863059	2
28	E2	fluoroether E2	DTXSID50880192	2
29	E1	heptafluoropropyl 1,2,2,2-tetrafluoroethyl ether	DTXSID8052017	2
30	E3	fluoroether E3	DTXSID10880193	2
31		carbonyl fluoride	DTXSID7059858	2
32	PAF	perfluoroacetyl fluoride	DTXSID6059867	2
33		n-perfluorobutane	DTXSID5059876	2
34	MA (?)	tetrafluoro-2-|tetrafluoro-2-(fluorosulfonyl)ethoxy]-propanoylfluoride	-	2
35		8-fluorosulfonylperfluoro(2,5-dimethyl-3,6-dioxaoctanoyl) fluoride	DTXSID40863318	2

36	PPF	perfluoropropionyl fluoride	DTXSID4059968	2
37	PPF Acid	perfluoropropionic acid	DTXSID8059970	2
38	DFSA	difluorosulfoacetic acid	DTXSID90349596	2
39	HFPO	hexafluoropropylene oxide	DTXSID6029177	2
40	EVE	methyl perfluoro(3-(1-ethenyloxypropan-2-yloxy)propanoate)	DTXSID8044969	2
41	RSU	2,2-difluoro-2- (fluorosulfonyl) acetyl fluoride	DTXSID0060981	2
42	MMF	2-fluoro-2-methylpropanedioyl difluoride (aka methyl-2, 2-difluoromalonyl fluoride or 2-fluoro-2-methylpropanedioyl difluoride)	-	2
43	MAE	methylperfluoro(5- (fluoroformyl)-4-oxahexanoate)	DTXSID70887648	2
44	DAE	methyl perfluoro(8-(fluoroformyl)-5-methyl- 4 7-dioxanonanoate	DTXSID90881284	2
45	SU	2- hydroxytetrafluoroethane sulfonic acid sultone	DTXSID7061017	2
46	NVHOS	1,1,2,2-tetrafluoro-2-(1,2,2,2-tetrafluoro-ethoxy)ethane sulfonate	DTXSID80904754	2
47	MTP	2,2,3,3-tetrafluoro-3-methoxy-propanoic acid	-	2
48	Byproduct 4	2,2,3,3,4,5,5,5-4-(1,1,2,2-tetrafluoro-2-sulfoethoxy)pentanoate	-	2
49	Byproduct 5	2-fluoro-2-[1,1,2,3,3,3-hexafluoro-2-(1,1,2,2-tetrafluoro-2-sulfoethoxy)propoxy]acetic acid	-	2
50	Byproduct 6	1,1,2,2-tetrafluoro-2-[(1,1,1,2,3,3,4,4-octafluorobutan-2-yl)oxy]ethane-1-sulfonic	-	2

		acid1,1,2,2-tetrafluoro-2-[(1,1,1,2,3,3,4,4-octafluorobutan-2-yl)oxy]ethane-1-sulfonic acid		
51	EVE Acid	2,2,3,3-tetrafluoro-3-[1,1,1,2,3,3-hexafluoro-3-(1,2,2-trifluoroethenoxy)propan-2-yl]oxypropanoic acid	DTXSID00880940	2
52	R-EVE	5-(2-carboxy-1,1,2,2-tetrafluoroethoxy)-2,2,3,3,5,7,7,7-octafluoroheptanoic acid	-	2
53	PFECA B	Perfluoro-3,6-dioxaheptanoic acid	DTXSID30382063	2
54	PFECA G	4-(Heptafluoroisopropoxy)hexafluorobutanoic acid	DTXSID60663110	2

In addition to these 54 compounds, there are numerous PFAS with likely human exposure associated with the Fayetteville facility that cannot be tested at the present time because they lack adequate chemical characterization. For example, a recent report of sampling conducted by Chemours under the North Carolina consent order identified 21 "unknown" PFAS present in General Facility Discharge samples and 250 "unknown PFAS" present in Chemours Process Wastewater samples, for a total of 257 potential unique "unknown" PFAS (14 unknown PFAS were present in both types of samples).[39] As the report explains, "the compounds are considered to be unknown because the analytical method has not been calibrated for them (for example, because authentic standards do not exist)" but there is sufficient information to determine that the unknown compounds are PFAS. This non-targeted analysis was conducted to "develop standards and methods to facilitate the quantitative analysis of" the unknown PFAS. As standards are developed and these PFAS can be fully identified, they may also warrant testing based on their presence in discharges from the Chemours facility.

VI. RATIONALE UNDER TSCA FOR REQUIRING TESTING ON THE 54 PFAS

A. Present an Unreasonable Risk of Injury to Health or the Environment

As shown below, all of the 54 PFAS individually meet the criteria in TSCA section 4(a)(1)(A) for requiring testing because (1) they may present an unreasonable risk of injury to health or the environment, (2) they lack sufficient data to determine their adverse health and environmental effects and risks of injury, and (3) testing is necessary to provide sufficient information for these determinations. In addition, it is likely that some PFAS activate similar biological processes and have additive or other interactive effects when there is concurrent exposure through drinking water or other pathways. These PFAS mixtures would likewise meet the TSCA testing criteria based on their potential for unreasonable risk and the insufficiency of available data on their effects on human health.

As described above, the "may present" standard in section 4 is not difficult to satisfy. The focus is on whether there is a reasonable basis for concern about a chemical, not whether there is certainty about

its risks to health or the environment. Neither hazard nor exposure need be conclusively demonstrated. It is only necessary to show that the possibility of both is more than theoretical; this can be established by inference rather than direct evidence. Thus, testing will be warranted where (1) data or structure-activity analysis indicate potential adverse effects and (2) there is reason to anticipate exposure to the chemical by people or the environment. For groups of chemicals that qualify as a "category" under section 26(c) because of similarities in chemical structure and/or toxicity, these determinations need not be made for every individual substance but can be based on the common characteristics of the class.

1. Heath Effects of PFAS as a Class

Available data on the PFAS class demonstrate a range of serious health effects in people and animals, including cancer, hormone disruption, liver and kidney damage, developmental and reproductive harm, changes in serum lipid levels, and immune system toxicity, some of which occur at extremely low levels of exposure.[4,7,40-45] Consistent evidence of these health effects has been observed in experimental animals as well as in people exposed at work or from drinking PFAS-contaminated water or in the general population, and this consistency increases confidence in a causal relationship between PFAS and health effects in humans.

PFOA and PFOS are two specific PFAS that have been studied most intensively. However a similar spectrum of health effects are associated with several other chemicals within the PFAS class, such as GenX, PFHxS, PFHxA, PFBuS, PFBuA, and PFNA.[3,4] These effects have been observed consistently in both short-chain and long-chain substances and should be presumed to be of concern for all PFAS. Thus, recent EPA and other governmental toxicity assessments and health advisories for PFOS, PFOA, GenX and PFBS identify similar health effect concerns over a range of PFAS compositions.[4,40,42,44]

Liver toxicity is the most common effect observed across the PFAS family, in both humans and experimental animals, likely because it is commonly measured. For example, a study in China found altered liver function markers in people with exposure to PFOA, PFOS, and PFNA and abnormal prealbumin associated with exposures to PFPeA, PFHxA, PFNA, PFDoDA, PFTrDA and PFTeDA.[46] Similarly, EPA's toxicity evaluation for GenX selected liver effects as the basis for the assessment, and also noted that other effects observed included kidney toxicity, immunological effects, developmental effects, and cancer, similar to PFOA, PFOS, and other PFAS that have been studied.[44]

As another example of consistent effects across the PFAS class, in a recent review article about PFAS chemicals[3], the US National Toxicology Program (NTP) concluded that findings of suppressed vaccine response in humans and T cell-dependent antibody response in experimental animals warranted classifying PFOA and PFOS as presumed immune hazards to humans.[47] In a recent draft toxicological profile, the ATSDR extended this finding to PFHxS and perfluorodecanoic acid (PFDeA), identifying all four compounds as suppressants of antibody response in humans.[4,47]

PFOA and GenX have been shown to cause cancers in experimental animals, particularly in the pancreas, and a large study of people exposed to contaminated drinking water near the DuPont facility in Parkersburg WV also found elevated rates of two cancers. A recent review of the carcinogenic potential of PFAS as a class[43] concluded that: "The most well-studied member of the PFAS class, perfluorooctanoic acid (PFOA), induces tumors in animal bioassays and has been associated with elevated risk of cancer in human populations. GenX, one of the PFOA replacement chemicals, induces tumors in animal bioassays as well. Using the Key Characteristics of Carcinogens framework for cancer hazard identification, we considered the existing epidemiological, toxicological and mechanistic data for 26 different PFAS. We

found strong evidence that multiple PFAS induce oxidative stress, are immunosuppressive, and modulate receptor-mediated effects."

EPA has analogized well-characterized PFAS like PFOS and PFOA to other chemicals in the class and concluded that, because these chemicals have the potential for the same adverse effects, they should be tested for the same endpoints and/or controlled to limit risks. For example, the 2009 TSCA section 5(e) consent order for GenX chemicals[9] -- which are short-chain PFAS – noted that: "EPA has concerns that these PMN substances will persist in the environment, could bioaccumulate, and be toxic ("PBT") to people, wild mammals, and birds. EPA's concerns are based on data on the PMN substances, analogy to other [PFAS] chemicals, and to perfluorooctanoic acid ("PFOA") and perfluorooctane sulfonate ("PFOS") which are both currently under review by EPA for PBT concerns." According to EPA:

> "Toxicity studies on the analogs PFOA and PFOS indicate developmental, reproductive and systemic toxicity in various species. Cancer may also be of concern. These factors, taken together, raise concerns for potential adverse chronic effects in humans and wildlife" from exposure to GenX. [9]

On this basis, the order determined that, "In light of the potential risk of human health and environmental effects posed by" GenX chemicals, their manufacture and processing "may present an unreasonable risk of injury to human health and the environment" and "the information available to the Agency is insufficient to permit a reasoned evaluation of the[ir] human health and environmental effects." To address these findings, the order placed controls on manufacture, use and disposal and required extensive health and environmental effects testing, including chronic/carcinogenicity studies.[9]

EPA applied the same approach in its 2015 proposed TSCA Significant New Use Rule (SNUR) for long-chain perfluoroalkyl carboxylate and perfluoroalkyl sulfonate substances.[48] Explaining why new uses of these substances should be prohibited without EPA review, EPA relied on their similarities to PFOS and concern that other PFAS would have the same health effects:

> "While most studies to date have focused primarily on PFOS, structure-activity relationship analysis indicates that the results of those studies are applicable to the entire category of PFAS chemical substances, which includes PFOS. Available test data have raised concerns about their potential developmental, reproductive, and systemic toxicity." [48]

Given the recognition of EPA and other authorities that all PFAS have the potential for causing the adverse health and environmental effects linked to well-characterized substances like PFOS and PFOA because of their common structural characteristics, there is a strong basis to conclude that the 54 PFAS covered by this petition "may present an unreasonable risk of injury" under TSCA section 4(a)(1)(A).

Magnifying this potential risk is the co-occurrence of multiple PFAS in drinking and surface water, other environmental media and the blood of humans and wildlife. This co-occurrence is amply demonstrated in the Cape Fear watershed, where numerous PFAS manufactured at the Fayetteville facility have been detected in the same samples of drinking water and surface water and human sera. Where exposure is to multiple PFAS simultaneously, their toxic effects may be additive or synergistic, resulting in greater overall risk than exposure to any individual PFAS alone.

2. Demonstrated and Anticipated Exposure to the 54 PFAS

As noted above, potential exposure is a component of a "may present" finding under section 4(a)(1)(A). Such exposure can be inferred from a substance's properties and circumstances of manufacture and use as well as from direct evidence of exposure. In the case of the 14 Tier 1 compounds, their presence in human blood, produce and/or drinking water, including for large community water supplies, demonstrates human exposure by a large population in the Cape Fear watershed, amply supporting a "may present" finding. For the remaining 40 PFAS in Tier 2, a strong inference of exposure can be drawn from their presence in surface water, stormwater, wastewater, sediment, groundwater, soil, private wells, and/or air emissions. These pathways are highly likely to result in direct exposure by residents of the surrounding region as well as by fish, birds, and wildlife. Moreover, over time, the probability of exposure will be heightened by the persistence, high mobility and bio-accumulative properties of PFAS, which result in their long-term residence and wide distribution in environmental media.

Although information is limited about the commercial chemical products that leave the Chemours facility, there are also multiple pathways that could result in exposure to the 54 PFAS outside of the Cape Fear watershed:

- GenX chemicals are transported to Chemours' Parkersburg, West Virginia facility for use in fluoropolymer production and have been detected in drinking water systems and private wells in the vicinity of the plant.[13] GenX has also been detected downstream in Louisville, Kentucky and in other locations.[12,14]

- Twelve of the 54 PFAS are used to manufacture products, like plastics (PSEPVE, PPVE), chemicals (PEPF, HFPO-DAF), and/or other raw materials (PSEPVE, PPVE, PEPF, HFPO-DAF) that are distributed in commerce.[49] These PFAS could be released into the environment or result in worker or population exposure at sites where the products are processed or used or at the end of their life-cycles, for example by incineration, landfilling or wastewater treatment. They could also result in food contact if they migrate from food packaging, an application in which PPVE is used.

- Four of the 54 PFAS are listed directly as ingredients in consumer products and can be expected to result in widespread exposure, while others are used in manufacturing of consumer goods.[49]

Specific uses of these 54 PFAS as reported in EPA's Chemistry Dashboard[50] based on Dionisio (2018)[49] are listed below in Table 2.

TABLE 2: PFAS KNOWN TO BE USED IN MANUFACTURING PRODUCTS BASED ON DIONISIO (2018)[49]

CHEMICAL NAME	**SUMMARY OF USES**
trifluoro(pentafluoroethoxy)ethylene	plastics manufacturing

tetrafluoroethylene	food and drinking water contact materials, plastics, sewage treatment
hexafluoropropene	food and drinking water contact materials, plastics, automotive, interior
trifluoro(trifluoromethoxy)ethylene	food and drinking water contact materials, plastics
1,1,2,2-tetrafluoro-2-[1,2,2-trifluoro-1-(trifluoromethyl)-2-[(trifluorovinyl)oxy]ethoxy]ethanesulphonyl fluoride	plastics manufacturing
1,1,1,2,2,3,3-heptafluoro-3-[(trifluorovinyl)oxy]propane	food and drinking water contact materials, plastics
propanoyl fluoride, 2,3,3,3-tetrafluoro-2-(pentafluoroethoxy)-	chemical manufacturing
2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionyl fluoride	chemical manufacturing
2,3,3,3-tetrafluoro-2-(trifluoromethoxy)propionyl fluoride	chemical manufacturing
decafluorobutane	drug manufacturing
2,3,3,3-tetrafluoro-2-[1,1,2,3,3,3-hexafluoro-2-[1,1,2,2-tetrafluoro-2-(fluorosulphonyl)ethoxy]propoxy]propionyl fluoride	chemical manufacturing
trifluoro(trifluoromethyl)oxirane	chemical and plastics manufacturing

- Chemours is now transporting its process wastewater off-site for deep well injection in Deer Park, Texas. Spills or accidents at the facility during the manufacturing process and during transport could release PFAS into the environment, and releases are also possible during or after injection. Furthermore, Chemours has stated its intention to resume wastewater discharges to the Cape Fear River, which will result in PFAS discharges even if the waste is treated first to reduce levels of PFAS.[51]

Thus, in addition to their presence in environmental media and biota in the Cape Fear region adjacent to and downstream of the Chemours facility, several of the 54 PFAS are likely a common source of exposure for a broad segment of the US population.

B. Insufficiency of Information and Experience

To justify testing, TSCA section 4(a)(1)(A) also requires EPA to determine that there are "insufficient information and experience" to reasonably determine or predict a chemical's effects on health or the

environment. For the 54 PFAS, the sufficiency of available information should be determined by comparing available data with the known adverse effects of other PFAS. The goal should be to conduct a scientifically sound assessment of each of the 54 chemicals for the critical toxic endpoints that have been identified in studies on PFOS, PFOA and other well-characterized substances. If such an assessment cannot be conducted for the 54 substances because of the lack of data, available information on these substances should be deemed "insufficient" under TSCA section 4(a).

As EPA stressed in its PFAS Action Plan,[7] "[t]here are many PFAS of potential concern to the public that may be found in the environment. Most of these PFAS lack sufficient toxicity data to inform our understanding of the potential for adverse human or ecological effects." The absence of toxicological data was underscored by ATSDR in its draft 2018 Toxicological Profile for PFAS,[4] which identifies numerous critical gap gaps across the PFAS class. The 54 substances covered by this petition fit this pattern. Either they lack any health and ecological effects data or the available studies are limited and incomplete and do not provide an adequate basis for hazard and risk assessment. Key data gaps include measurement of physical-chemical properties, methods of analysis, assessment of partitioning, bioaccumulation, and degradation, pharmacokinetics, and toxicity, especially for the endpoints commonly observed for the better studied PFAS, such as liver toxicity, and effects on the immune system, lipid metabolism, kidney, thyroid, development, reproduction, and cancer. In addition, despite their widespread detection in environmental media, ecotoxicity data are generally lacking.

While testing has been conducted on GenX and Chemours is required to test five other PFAS under the North Carolina consent order, this testing is inadequate to fully evaluate the risks of these substances. For example, EPA's draft 2018 Toxicity Assessment for GenX chemicals[44,52] highlights the need for additional carcinogenicity studies:

> "One study is available on evaluating carcinogenicity of HFPO dimer acid and its ammonium salt in rats (DuPont-18405-1238, 2013). In this study, liver and pancreatic tumors were noted at the highest doses tested. The available data for HFPO dimer acid ammonium salt suggest that mice might be more sensitive to exposure to these GenX chemicals than rats. Given the evidence that the liver is the target organ for toxicity and the primary organ for tumor development, there is aneed for additional research using chronic duration exposures in mice."

Echoing concerns in EPA's PFAS Action Plan, the EPA draft GenX toxicity assessment[44,52] also notes that "[n]o data are available to evaluate cancer risk via dermal or inhalation exposure" and that "[d]ata for the elucidation of differential susceptibility dependent on life stage (e.g., developing fetus, women of reproductive age, or pregnant women) are not available."

Comments on the EPA draft GenX toxicity assessment[52] by CEH and other groups also highlighted the "[l]ack of toxicity data from inhalation and dermal exposure routes" and underscored the need for additional developmental toxicity and immunotoxicity studies:

> "Developmental toxicity and immunotoxicity are common health effects associated with PFAS exposure, both of which can occur at extremely low levels of exposure.[4] Two developmental toxicity studies, only one of which was in mice, and a single study that specifically assesses immune effects is a serious database limitation.

> One critical data gap is the lack of a full 2-generation toxicity study evaluating exposures during early organogenesis. Additionally, there are many developmental and immune effects that have yet to be assessed, including reproductive system development (i.e. mammary gland development and function), neurodevelopment, autoimmunity, infectious disease resistance, and immune hypersensitivity (i.e. asthma and allergies)."

A recent study comparing the toxicity of PFOA and GenX in pregnant mice and their developing embryo–placenta units demonstrated a similar increase in placental abnormalities relative to controls for both compounds, underscoring concern about GenX's reproductive effects and the need for additional data.[53] The testing program proposed by petitioners would address these GenX data-gaps.

Similarly, while the testing program for 5 PFAS called for by the North Carolina consent order is a step in the right direction, it falls short of providing sufficient information for an informed assessment of these chemicals' health effects. The five substances are all listed in Tier 1 because of demonstrated human exposure, as evidenced by their presence in human sera, produce and/or drinking water. Nonetheless, the studies to be conducted consist only of 28-day oral immunotoxicity studies and 90-day oral repeated dose toxicity studies in rats and mice. Not included are studies on reproduction/developmental toxicity, carcinogenesis, toxicokinetics and fate and transport, which are essential for risk evaluation. In addition, testing is only by the oral route and so inhalation and dermal toxicokinetic studies are important for those substances for which exposure is predominantly by these routes. These gaps would limit understanding of the health effects of the five substances and impede assessment of the risks of historical, ongoing and future exposure which is essential for public awareness, public health protection and informed risk management. The testing program proposed in this petition for Tier 1 chemicals would develop this missing information.

C. The Need for Testing to Develop Sufficient Information

A final prerequisite for issuing a test rule under section 4(a)(1)(A) of TSCA is a finding that testing "is necessary" to determine the health and environmental effects for which sufficient information is lacking. The studies proposed by petitioners are the minimum necessary for a full understanding of the health risks from past present and future exposure to the 54 PFAS by petitioners, their families and the communities they represent and for health protective reductions in risk and exposure going forward.

A strong focus of this petition is toxicity testing in experimental animals. These studies are "necessary" under TSCA because no alternative to animal testing is capable of developing reliable health effects information on individual PFAS at this time.

As described above, PFOA, PFOS and other PFAS are known to cause common modes of toxicity in vivo, such as effects on liver biochemistry and cholesterol[54], pup survival[55], and immunotoxicity.[38,56] However, the mechanisms and molecular initiating events associated with these effects have not been defined. As a result, in vitro assays or computational approaches that reliably predict in vivo effects are not currently available or validated for PFAS. A recent peer-reviewed paper from EPA scientists[57] explains that the Agency is conducting in vitro testing on 75 PFAS in order to develop and validate approaches to predict PFAS toxicity based on molecular structure. However, this work is still at an early stage and only two of the PFAS covered by this petition are included in the EPA testing.[57]

In addition, the toxicokinetics of PFAS are unpredictable, making it difficult to anticipate relationships between intake and serum or tissue concentrations.[4,28,54,58] Testing in experimental animals, including toxicokinetics and endpoint-specific studies, is necessary to address these uncertainties. A recent scientific meeting report focused on PFAS concluded that: "Differences in bioactivity, and/or kinetics that are not consistently explained by structure alone necessitate prioritization of collection of additional toxicity data associated with representative molecules." The report adds "that traditional tools used for organic molecules to predict fate and transport are generally not helpful in predicting outcome for this group of substances highlighting the need for new approaches and models that could be useful for fluorinated organic molecules."[58]

Animal studies alone, however, are not sufficient for understanding the human health effects of PFAS exposure. The half-lives of PFAS may vary between chemicals and between species, sexes, and developmental stages, and this variability appears to drive some of the apparent differences in toxicity (e.g. see ATSDR 2018).[4,54] Moreover, human half-lives are not confidently predicted from animal studies, although these studies can provide important information about biological persistence.[4] Thus, the best approach is a combination of toxicokinetic studies in rats and mice and longitudinal biomonitoring studies in workers when they are starting or ending their exposure. These studies, accordingly, are likewise "necessary" under TSCA for informed risk assessment and management. This petition would require Chemours to fund and facilitate them.

Finally, exposures around the Fayetteville facility and by the downstream communities that petitioners represent have been to multiple PFAS simultaneously. Although animal toxicity studies on individual PFAS are essential, they do not account for the synergistic and cumulative effects of multi-compound exposures. In order to understand the effects of exposure to the PFAS mixtures originating from the Chemours facility, two additional studies are necessary. First, the petition proposes animal toxicity testing of three PFAS mixtures that represent characteristic exposures of residents in the Cape Fear watershed. Second, the petition proposes a study of PFAS-associated health outcomes in exposed residents in the watershed. Both of these studies are "necessary" under TSCA because they are the only way to examine the health impacts from exposure to the mix of PFAS chemistries uniquely associated with the North Carolina operations of DuPont and Chemours. The petition proposes to study three PFAS mixtures that replicate actual exposure pathways using the same toxicology tests specified for the 54 individual PFAS, as specified below. The proposed epidemiologic study would be based on the approach successfully used in Parkersburg WV to examine the human health impacts of PFOA exposure (the "C8 Study").[59] [60]

As discussed below, this petition also proposes ecotoxicity studies, which EPA has previously determined are necessary because of the widespread presence and mobility of PFAS in environmental media, and studies of physical-chemical properties and fate and transport, which are necessary for both human health and environmental risk assessment for the 54 substances.

VII. FRAMEWORK FOR PROPOSED TESTING PROGRAM

A. General Approach to Testing

Once EPA makes the findings justifying testing under section 4(a)(1)(A) , it must require studies that will "develop information with respect to the health and environmental effects for which there is an insufficiency of information and experience" and which are "relevant to a determination" whether the substance "does or does not present an unreasonable risk to health and the environment." Consistent

with this requirement, the petition calls for Chemours to perform toxicity studies on the 54 chemicals which address the endpoints associated with critical effects that have previously been the basis for evaluating the risks of PFOA, PFOS, and other studied PFAS. As discussed above, studies on these compounds show a generally similar or overlapping set of adverse effects, including cancer, hormone disruption, liver and kidney damage, developmental and reproductive harm, changes in serum lipid levels, and immune system toxicity.[3,4,42,44] These effects have in turn been selected as the basis for health-based guidelines for drinking water and other pathways of exposure.[4,40,42] The proposed testing approach for the 54 PFAS takes advantage of this existing knowledge by specifying studies that target critical effects that likely overlap with those that have been demonstrated by more extensive testing of PFOA, PFOS and other studied PFAS, recognizing that potency and toxicokinetics may vary by compound and endpoint. The endpoints to be addressed in these studies are described below:

B. Human Health Effects Studies on the 54 PFAS in Experimental Animals

For all 54 compounds, the following critical human health endpoints should be investigated:

1. Liver toxicity: Effects on liver are commonly reported for PFAS studies in humans and animals[3,4] and this effect was selected as the basis for risk assessments for drinking water guidelines for several PFAS in several states, including California, Maine, New Jersey, and North Carolina (PFOA); Canada (PFOS); and EPA (GenX).[42,44] Blood biochemistry markers that reflect liver toxicity, such as ALT, are altered in animal and human studies of PFAS exposures, e.g. Nian (2019).[46] Studies in exposed humans have also shown that PFAS affect serum levels of cytokeratin 18 M30, tumor necrosis factor α, and Interleukin 8.[61]

2. Serum biochemistry including cholesterol, lipids, glucose: PFAS appear to affect metabolism and effects on cholesterol and lipid levels have been reported in humans and animals.[3,4,17,62] Other serum biochemical markers are related to PFAS effects on liver and kidney.

3. Immunotoxicity: Immunotoxicity, especially reduced antibody response, has been reported for PFOS, GenX, and other PFAS in animals and humans, and US NTP has categorized PFOA and PFOS as presumed human immunotoxicants.[4,38,44,47,63-65] The effects reported for PFOS in the Dong (2009) animal study[38] are the basis for the New Jersey drinking water guideline for PFOS.

4. Developmental and reproductive toxicity, especially pup body weight and mortality: Risk assessments to set drinking water guideline levels for PFOA and PFOS have often been based on pup weight and pup mortality in the 4 days after birth, as well as on other developmental effects.[4,40,42] Specifically, the Lau (2006) study[55] of PFOA shows important effects on pup viability at low exposures and this study has driven several governmental risk assessments.

5. Kidney toxicity: While kidney toxicity does not appear to be the critical effect for PFOA, PFOS, or GenX, kidney effects are commonly reported in rodents and humans.[3,4]

6. Thyroid hormones: PFAS exposures affect thyroid hormone levels in multiple studies. Thyroid was a critical effect for EPA's PFBS risk assessment.[44]

For Tier 1 compounds with demonstrated human exposure in human sera and/or drinking water, the following additional critical endpoints would be addressed:

1. Developmental neurotoxicity: Michigan set its drinking water guideline for PFOA based on developmental neurotoxicity and Texas set its PFOS guideline based on altered hippocampus synapse structure.[42] Maine set a drinking water remediation guideline for PFOA based on thyroid hormone changes,[40] and EPA added a 3X uncertainty factor in the GenX risk assessment because of the lack of data for developmental neurotoxicity and immunotoxicity assessments.[44] Thyroid was a critical effect for EPA's PFBS risk assessment.[44]

2. Developmental immunotoxicity: As noted above immunotoxicity has been observed in rodent and human studies for several PFAS, and EPA added a 3X uncertainty factor in the GenX risk assessment because of the lack of data for developmental neurotoxicity and immunotoxicity assessments.[44]

3. Developmental reproduction including mammary gland development: US EPA and Minnesota set their drinking water guidelines for PFOA based on accelerated puberty. Texas set theirs based on altered mammary gland development and New Jersey highlighted altered mammary gland development as a critical effect of concern. The altered mammary gland development from early life exposure is linked to impaired lactation in rodent studies.[66,67] Effects on the developing male and female reproductive system have been reported for several PFAS.[4]

4. Carcinogenesis: PFOA and GenX have been tested in cancer bioassays and found to cause pancreatic, liver, and other tumors, and studies in humans showed elevated kidney and testicular cancers.[4,44,45] California has based drinking water guidelines on these cancer effects.[42]

For all 54 compounds, an informed risk evaluation will also require studies to characterize toxicokinetics in the test animal species, including parameters necessary to anticipate internal doses associated with oral, dermal, and inhalation exposures in humans. Also, all toxicity studies would verify internal doses with serum or other tissue concentrations.

Previous PFAS animal testing has been conducted mainly by the oral route of exposure. This route is appropriate for evaluating risks of ingesting PFAS-contaminated drinking water. However, inhalation and dermal contact are also known pathways of exposure for some PFAS. Previous testing has rarely examined the effects of PFAS exposure by these routes. As EPA acknowledges in its PFAS Action Plan, "[l]imited data exist on health effects associated with inhalation or dermal exposure to PFAS."[38] As noted above, EPA's draft toxicity assessment for GenX and public commenters have highlighted the absence of information to assess risks from inhalation and dermal exposure.[44] For the testing proposed in this petition, studies would be carried out by oral routes of administration, except inhalation would be used for volatile chemicals. (Within the set of 54 chemicals, ten have an estimated boiling point above 30° C. and an additional nine have an estimated vapor pressure above 10 mm Hg, indicating these may be candidates for inhalation testing.)

For several end-points and routes of exposure, testing should be conducted in two species, i.e. rats and mice, as EPA indicated in its GenX toxicity assessment. The proposed testing plan specifies which tests should be conducted in both rats and mice vs. in just one species.

All PFAS studies should be designed to measure levels of the test compound and any potential metabolites (though these are unlikely to occur) in sera or urine in order to verify internal dose and correlate administered and internal doses with adverse effects, including for different routes of administration.

C. Animal Studies on PFAS Mixtures

As noted above, while studies on individual PFAS provide critical information, they do not account for the synergistic and additive effects of simultaneous exposure to multiple PFAS and likely will understate the severity of health effects as a result. In the Cape Fear watershed, actual exposure has been to mixtures of PFAS in drinking water, augmented by concurrent exposure to PFAS in ambient air and local produce. To capture the interactions between the multiple PFAS to which local populations have been exposed, this petition proposes that representative PFAS mixtures undergo the same set of animal studies as the 54 individual compounds. To conduct this testing, three PFAS mixtures would be formulated and administered, reflecting distinct subgroups in the exposed population: : 1) the mixture of PFAS detected in drinking water consumed by Cape Fear communities downstream of the Chemours plant; 2) the mixture of PFAS found in the blood of area residents during bio-monitoring; and 3) the mixture of compounds to which residents living near the Chemours facility have been exposed as a result of plant emissions and discharges (i.e. PFAS measured in ambient air, private wells, and local produce).

D. Human Studies of Communities Exposed to PFAS-contaminated Drinking Water

TSCA section 4(b)(2)(A) authorizes EPA to require human epidemiology studies. Because of the extensive exposure to PFAS by communities in the larger Cape Fear watershed, it is important to better understand the levels and extent of PFAS exposure, the specific PFAS present in blood and urine and the medical histories of individuals in this population and to examine the association between these indicators of PFAS exposure and health outcomes. Studies in humans are an important way to identify health effects associated with the combined exposure to many PFAS, and to take into account toxicokinetics or susceptibilities that are unique to humans but not measured in rodent toxicity studies.

A research study to determine the health impacts of PFOA exposure was conducted under the settlement in the class action suit against DuPont for PFOA drinking water contamination near the DuPont/Chemours Washington Works in Parkersburg, West Virginia.[68] To conduct this study, medical histories and blood samples were obtained from residents of the affected water districts (roughly 80,000 people) and then the data were reviewed by a Science Panel comprised of three respected epidemiologists. The Panel conducted a number of additional studies based on the data and ultimately reached a conclusion that it was “probable” that exposure to PFOA in drinking water was linked to testicular and kidney cancer in the impacted communities, along with additional serious non-cancer human diseases.[69,70]

The West Virginia study – taken together with recent studies in other contaminated regions that show links between PFAS exposure and immune response,[64,65] serum lipids,[61,62] and birth outcomes[71] (all

outcomes that are also observed in toxicology studies although generally humans appear more sensitive) – confirms the value of epidemiological data for other populations exposed to PFAS, including in Eastern North Carolina. The Cape Fear River is a source of drinking water for over 250,000 local residents downstream of Fayetteville and has been contaminated by multiple PFAS linked to the Chemours facility. Thus, there is an opportunity to examine whether health effects have occurred in this population due to drinking water exposure to a unique set of PFAS chemicals. A study modeled after the C8 Study in Parkersburg, West Virginia would provide important data about associations between measured and historically reconstructed PFAS exposure levels and selected health outcomes.

This study should[60] recruit at least 100,000 children and adults (equally of both sexes for both children and adults) from communities exposed to PFAS-contaminated drinking water. The study should obtain blood samples from participants to measure PFAS serum levels and several effect biomarkers such as lipids, and thyroid, kidney, immune and liver function. The study would also obtain urine samples from participants to measure PFAS levels and kidney function biomarkers. Based on this information, the study would examine associations between exposure to PFAS compounds and lipids, renal function and kidney disease, thyroid hormones and disease, liver function and disease, glycemic parameters and diabetes, as well as immune response and function and cancers in both children and adults. In addition, the study would investigate PFAS differences in sex hormones and sexual maturation, vaccine response, and neurobehavioral outcomes in children. In adults, additional outcomes of interest would include cardiovascular disease, osteoarthritis and osteoporosis, endometriosis, and autoimmune disease.

ATSDR has selected research teams to implement an epidemiologic study in seven communities where people have experienced drinking water contamination from PFAS.[60] Unfortunately, no research proposal was submitted for the Cape Fear/Wilmington communities despite their history of drinking water contamination with PFAS from the Chemours Fayetteville facility. We believe that TSCA section 4 provides authority to direct Chemours to fund an epidemiological study of these communities. Such a requirement would be based on the finding (discussed above) that PFAS releases from the facility "may present an unreasonable risk of injury" to the health of impacted communities. In addition, since animal toxicology studies do not reflect the effects of combined exposure to multiple PFAS human and animal response may differ because of toxicokinetics and other factors, there is "insufficient information and experience" to reasonably determine or predict the health effects of the 54 PFAS in the absence of human data. We request that EPA therefore include a human study in the test rule or order it issues in response to this petition.

E. Human Half Life Studies

As noted above, the half-lives of PFAS may vary between chemicals and between species, sexes, and developmental stages, and this variability appears to drive some of the apparent differences in toxicity. Moreover, half-lives in humans may not be predicted from animal studies. Thus, to determine half-lives in humans, we propose that Chemours conduct longitudinal studies in its workers to detect the rate of increase and rate of decay of serum or tissue levels as exposure begins or ceases.

F. Physical-Chemical Properties and Fate and Transport Studies and Test Standards

i. Fate and Transport Studies

EPA's PFAS Action Plan recognizes that "Information for many PFAS sources, fate and transport, and human and ecological exposure is sparse, both spatially and temporally."[7,41] In addition to toxicity testing in animals and humans, conducting risk evaluations for these 54 chemicals will require the ability to effectively identify and quantify concentrations of the chemicals in various media. Thus, additional testing is necessary to evaluate fate and transport for the 54 PFAS, including their propensity to bioaccumulate, bind to organic material, partition to air or water, and degrade under various conditions.

The EPA OPPTS 835 series of tests addresses fate and transport characteristics and notes that "Information on the degradability of organic chemicals may be used for hazard assessment or for risk assessment under TSCA." Here too, testing conducted on GenX at EPA direction provides a model for fate and transport studies on other PFAS. In the GenX PMNs, Chemours (then DuPont) submitted studies for thermal transformation byproduct ready biodegradability and activated sludge respiration inhibition. The EPA consent order following review of these PMNs required several additional studies as listed in Table 3 below:

TABLE 3: REQUIRED FATE AND TRANSPORT TESTS FOR THE 54 PFAS

ENVIRONMENTAL FATE TESTING	**OPPTS OR OECD GUIDELINE**
Modified Semi-Continuous Activated Sludge (SCAS) with Analysis for degradation products	OPPTS 835.5045, OPPTS 835.3210 or OECD 302A
Aerobic and Anaerobic Transformation in Soil	OECD 307
Aerobic and Anaerobic transformations in Aquatic Sediment Systems	OECD 308
Direct Photolysis in Water (if wavelengths >290 nm are absorbed)	OPPTS 835.2210
Indirect Photolysis in Water	OPPTS 835.5270
Phototransformation of Chemicals on Soil Surfaces	OECD Jan. 2002 Draft
Simulation test-Acrobic Sewage Treatment (Activated Sludge Units)	OECD 303A
Anaerobic biodegradability of organic compounds in digested sludge	OECD 311
Fish Bioconcentration test	OPPTS 850.1730

The studies included in the GenX PMNs and consent order should be performed on the 54 PFAS. (See Table 4a below.)

2. Physical-Chemical Properties Studies

Tests to characterize these chemicals' physical-chemical properties should also be conducted if they have not already been performed by Chemours. The EPA recently issued a test order for physical-

chemical data for Pigment Violet 29, one of the first chemicals subject to a TSCA risk evaluation, indicating the importance of this type of data for assessing risk under TSCA.[72]

According to the 2009 consent order issued by EPA,[9] the PMNs for GenX compounds included the following tests of physical-chemical properties: water solubility, vapor pressure, and octanol water partition coefficient. The consent order required two additional physical/chemical property tests: for UV visible absorption (OPPTS 830.7050 or OECD 101) and hydrolysis as a function of pH (OPPTS 830.7050 or OECD 111). We are adding one additional test to determine the octanol:air partition coeeficient. Taken together, these comprise a minimum set of physical-chemical properties tests that should be performed on the 54 PFAS, if not previously conducted.

3. Test Standards

.

While Chemours has apparently developed test standards for several PFAS measured in environment media, these standards are not readily available to the public and their adequacy cannot be assessed. To the extent they do not now exist, Chemours should develop valid analytical tools for detecting and measuring the presence of the 54 PFAS in the environment. For example, for pesticide registrations, EPA requires registrants to provide an analytical standard to ensure that the chemical can be identified with confidence in environmental or tissue samples. The EPA method notes that: "Proper analytical reference grade materials [should be] available for the Agency to validate residue and environmental chemistry analytical methods and that Federal and State enforcement laboratories have a known consistent source of analytical reference standards to validate methods employed in enforcement and monitoring activities"(EPA method OPPTS 860.1650).

G. Eco-toxicity Testing

EPA's PFAS Action Plan recognizes that "[e]cological toxicity information is also needed by stakeholders to inform risk assessment and management to protect ecosystems, animals, and plant resources they support, and ultimately the human benefits that stem from these resources, including, for example, the prevention of potential PFAS risks associated with consuming game animals and fish."[7,41] An understanding of the eco-toxicity of the 54 PFAS is critical because many of them have been detected in surface water and in aquatic species and, if persistent, bio-accumulative and mobile, will be widely found in fish, wildlife and other biota and may migrate up the food chain.

The 2009 consent order for GenX compounds finds that "there is high concern for possible environmental effects over the long-term," citing the GenX analog PFOA, "which has been detected in a number of species of wildlife, including marine mammals [and] is toxic to mammalian and other species."[9] Noting that the 2008 Dupont PMNs contained the results of acute toxicity testing of fish (Rainbow trout, daphnia, and algae), the consent order requires three additional studies – a Fish Early Life Stage Toxicity test (OPPTS 850.1400), a Daphnid Chronic Toxicity test (OPPTS 850.1300), and an Avian Reproduction test-Bobwhite Quail (OPPTS 850.2300). A similar but narrower set of studies is required for the 5 PFAS to be tested under the North Carolina consent order.[27]

The ecotoxicity end-points addressed in the 2008 PMNs and the 2009 consent order define a minimum set of environmental effects studies that should be performed on the 54 PFAS covered by this petition.

F. Avoiding Duplicative Testing

As discussed above, 5 of the 54 listed chemicals in this petition are also designated for testing in the Chemours North Carolina consent decree.[27] These tests would not need to be replicated in response to this petition. Similarly, GenX has undergone several studies under EPA's 2009 PMN consent order[9] and those tests would also not be repeated. However, GenX and the five PFAS subject to testing under the Chemours consent decree would require additional studies under the framework presented in this petition and these studies would need to be conducted under the test rule or order issued if the petition is granted.

In addition, the North Carolina consent order requires Chemours to submit all known analytical test methods and lab standards for PFAS in air emissions and process wastewater. Under a TSCA consent order or rule, Chemours would not need to develop additional test methods and standards where they have already been developed and submitted under the consent order. This would also be the case for fate and transport, physical-chemical properties and ecotoxicity studies already conducted.

VIII. SPECIFIC STUDIES TO BE CONDUCTED AND RELEVANT TEST GUIDELINES

Based on the testing framework described above, Table 4 lists the specific studies to be required and relevant test guidelines if the petition is granted.

TABLE 4A- TESTING NEEDED FOR ALL PFAS IN THE PETITION (TIERS 1 AND 2) AS WELL AS THREE PFAS MIXTURES

Type of test	EPA or other method number	Special requirements
Basic chemistry, physical-chemical properties, fate and transport, analytical standards		
Provide analytical standard to EPA	OPPTS 860.1650	
Product identity, composition, and analysis	OPPTS 830.1550, 1600, 1620, 1650, 1670, 1700, 1750, 1800, 1900	
Physical/chemical properties	OPPTS 830.7200, 7220, 7300, 7840, 7860, 7950, 7370, 7550, 7560, 7000, 7050	Melting point, boiling point, density, water solubility, vapor pressure, dissociation constant, octanol-water partition coefficient, octanol-air partition coefficient, pH, UV/Vis absorption, hydrolysis as a function of pH
Fate and transport	OPPTS 835 series tests, OPPTS 835.5045, OPPTS 835.3210 or OECD 302A, OECD 307, OECD 308, OPPTS 835.2210, OPPTS 835.5270, OECD Jan. 2002 Draft OECD 303A, OECD 311, OPPTS 850.1730	Various soil, sediment, and water transformation tests, fish bioconcentration, thermal transformation byproduct ready biodegradability, activated sludge respiration inhibition

Toxicity		
Combined repeated dose toxicity study with repro/dev tox screening test, oral This approximately 55-day test will be done to screen for effects on liver, lipid metabolism, immunotoxicity, and developmental toxicity This study would be conducted on all 54 chemicals as well as on three PFAS mixtures that represent what local residents have been exposed to.	EPA method 870.3650, with modification	2 species Oral (or by inhalation for higher vapor pressure chemicals) For this study, must use a modified protocol similar to that required for GenX in the TSCA test order to DuPont[9] and similar to the Lau et al. 2006 PFOA study. [55] Requirements for the study include (1) include 45 dams in control group, 25+ dams in each treatment group; (2) the duration of the study should be extended to until the pups have reached sexual maturation; (3) dosing of the parental animals should be continued through lactation and then the pups should be directly dosed until they reach sexual maturation; (5) pup body weight should be recorded on lactation days 0, 4, 7, 14, and 21 and then at weekly intervals, (6) litter size can be standardized to 4 male and 4 female pups/litter on lactation day 4 (optional); (7) at weaning one pup/sex/litter shall be randomly selected to follow until sexual maturation; and (8) the time of sexual maturation should be recorded (i.e. vaginal opening and preputial separation).) Critical endpoints: liver weight and histology liver lipid content kidney weight serum biochemistry, including ALT, lipids (including subfractions and lipoproteins),[62] glucose, cytokeratin 18 M30, tumor necrosis factor α, and Interleukin 8[61] pup weight and survival, pup liver/body weight ratio, and all other maternal and pup endpoints affected by PFOA in Lau et al 2006 pup and maternal liver gene expression spleen and thymus weights bone marrow cellularity maternal and pup hormone levels including thyroid hormones T4 and TSH, estradiol, and androgens mammary gland histopathology at puberty Plus all other standard endpoints

		Serum or urine concentrations of the dosed chemicals must be measured to ascertain internal dose; and tissue concentrations on some of the repeated dose animals is needed to understand absorption, distribution, and excretion.
Immunotoxicity This 28-day test in mouse includes T-cell dependent antibody responses and natural killer cell activity This study would be conducted on all 54 chemicals as well as on three PFAS mixtures that represent the groups of PFAS that local residents have been exposed to.	EPA method 870.7800	Oral (or by inhalation for higher vapor pressure chemicals) Use similar number of animals as in Dong et al. (2009)[38] PFOS study Standard endpoints in addition adding any additional endpoints reported in Dong et al. (2009) PFOS study Serum or urine concentrations of the dosed chemicals must be measured to ascertain internal dose
Toxicokinetics		
Toxicokinetics investigations should determine half-life in test species used for the toxicity testing and measure tissue concentrations including in fetal liver This study would be conducted on all 54 chemicals as well as on three PFAS mixtures that represent the groups of PFAS that local residents have been exposed to.	EPA 870.7485 tier 1, with modification to include pregnant animals	This testing should be conducted in all the species used for toxicity testing, in males and females, by oral, inhalation, and dermal routes of exposure, and in pregnant animals. Determine serum half-life, any tissues where bioaccumulation occurs, and any metabolites or transformation products. Determine the relationship between administered dose and serum and tissue concentrations. Based on this information, propose best method and matrix for biomonitoring in humans
Ecotoxicity	Same testing as was included in the GenX PMNs and required	1) acute toxicity testing of fish (Rainbow trout), daphnia, and algae

These studies would be conducted on all 54 chemicals as well as on three PFAS mixtures that represent the group of PFAS That local residents have been exposed to.	in EPA 2009 consent order w/ DuPont[9]	2) a fish early life stage toxicity test (OPPTS 850.1400), 3) a daphnid chronic (reproduction) toxicity test (OPPTS 850.1300), 4) sediment 10-day freshwater invertebrates toxicity test 5) an avian reproduction test-bobwhite quail (OPPTS 850.2300)

TABLE 4B- ADDITIONAL TESTING NEEDED FOR PFAS WITH DOCUMENTED HUMAN EXPOSURE (TIER 1)

Type of test	EPA or other method number	Special requirements
Extended one-generation with developmental immunotoxicity, reproductive toxicity, and neurotoxicity batteries and assessment of mammary gland development and hormone concentrations	NTP multigeneration[73] and OECD 443	Rats should be used for this assessment, except mice should be used for for developmental neurotoxicity assessment Parental males should be dosed for 10 weeks prior to mating; Standard endpoints plus hormone measurements (estradiol, androgens, T4, T3, TSH, glucocorticoids) mammary gland developmental and lactational effects (specifically, must assess whether the F1 can successfully feed the F2) pup and maternal liver gene expression and PPAR receptor levels developmental immunotox developmental reproduction developmental neurotoxicity in mice (learning and memory, motor, behavioral) Serum or urine concentrations of the dosed chemicals must be measured to ascertain internal dose
Carcinogenesis	2-year cancer bioassay	Rats and mice, males and females, including developmental exposure Standard endpoints Serum or urine concentrations of the dosed chemicals must be measured to ascertain internal dose

TABLE 4C: HUMAN STUDIES

Human half-life determination	Design longitudinal studies in Chemours workers to detect rate of increase and rate of decay of serum or tissue levels as exposure begins or ceases in order to determine half-lives in humans.

Epidemiological study of residents exposed to PFAS from contaminated drinking water from Cape Fear River and other pathways	Study health outcomes associated with past and current exposures in residents exposed to contaminated drinking water from Cape Fear River. A design similar to the C8 Study in Parkersburg WV is appropriate, given that an estimated 250,000 people downstream of the Chemours plant are served by drinking water with PFAS contamination. The study will include biomonitoring and historical exposure reconstruction taken together with reporting of relevant health outcomes including birth weights, ability to breast feed, liver and kidney function, cholesterol and blood chemistry, immune function, vaccine response, autoimmune diseases, and cancer. To be adequately powered, the study should enroll 100,000 or more residents. The study should examine a separate subgroup of residents close to the Chemours plants whose exposures were different from the rest, dominated by emissions of PFAS to air and subsequent inhalation and drinking water contamination from private wells and contamination of locally grown foods.

IX. MECHANISMS FOR CONDUCTING TESTING

As required under TSCA, Chemours would be legally responsible for carrying out testing in compliance with the EPA rule or order, which would prescribe in detail the protocols and methodologies for conducting testing, deadlines for completing testing and submitting results and requirements for filing progress reports and describing data and findings.

However, as a landmark testing program on a visible and important class of chemicals, it will be critical to assure that the required studies are performed independently and according to the highest scientific standards and are subject to rigorous oversight by EPA and outside experts. To maximize the credibility and objectivity of the data and key findings, EPA should ask the National Academy of Sciences (NAS) to create an independent expert science panel with responsibility for overseeing all aspects of the testing program. The panel's members would be appointed by NAS, with input from Chemours, the co-petitioners and other members of the public. This panel would provide direction on all aspects of study design, including selection of laboratories, protocols and methodologies, selection of dose levels, histopathology and statistical analysis of data and data interpretation and findings.

CONCLUSION

Petitioners look forward to meeting with EPA to discuss this petition and the Agency's response and appreciate the opportunity to present our concerns and recommendations for testing under TSCA section 4 on PFAS of great concern to the citizens of Eastern North Carolina.

Respectfully submitted,

Center for Environmental Health
Thomas R. Fox
Senior Policy Advisor
tom@ceh.org

Cape Fear River Watch
Dana Sargent
Executive Director
dana@cfrw.us

Clean Cape Fear
Emily Donovan
Co-Founder
esdonovan@gmail.com

Democracy Green
Jovita Lee
lee.jovita93@gmail.com

Toxic Free NC
Alexis Luckey
Executive Director
alexis@toxicfreenc.org

The NC Black Alliance
La'Meshia Whittington
LaMeshia@ncblackalliance.org

Robert M. Sussman
Sussman and Associates
3101 Garfield Street, NW
Washington DC 20008
202-716-0118
bobsussman1@comcast.net

Counsel for Petitioners

Ruthann Rudel. PhD
Director of Research
Silent Spring Institute
320 Nevada Street
Newton MA 02460
617-332-4288 ext. 214
www.silentspring.org

Drake Phelps
PhD Candidate
Department of Molecular Biomedical Sciences, College of Veterinary Medicine North Carolina State University
(434) 728-4293
drake_phelps@me.com

Science Advisors to Petitioners

REFERENCES

1 Wang, Y. *et al.* A review of sources, multimedia distribution and health risks of novel fluorinated alternatives. *Ecotoxicology and Environmental Safety* **182**, doi:10.1016/j.ecoenv.2019.109402 (2019).

2 US EPA. *Addition of Certain PFAS to the TRI by the National Defense Authorization Act*, <https://www.epa.gov/toxics-release-inventory-tri-program/addition-certain-pfas-tri-national-defense-authorization-act> (2020).

3 Kwiatkowski, C. Scientific Basis for Managing PFAS as a Chemical Class. *ES&T* (2020).

4 ATSDR. DRAFT Toxicological Profile for Perfluoroalkyls. (2018).

5 Hu, X. C. *et al.* Detection of Poly- and Perfluoroalkyl Substances (PFASs) in U.S. Drinking Water Linked to Industrial Sites, Military Fire Training Areas, and Wastewater Treatment Plants. *Environ Sci Technol Lett* **3**, 344-350, doi:10.1021/acs.estlett.6b00260 (2016).

6 US EPA. PFOA Stewardship Program. (2006).

7 US EPA. EPA's PFAS Action Plan. (2019).

8 Hogue, C. Confronting Fluoroethers. *Chemical & Engineering News* (2018).

9 US EPA. Consent Order regarding DuPont Premanufacture Notices P08-508 and P09-509. (2009).

10 Strynar, M. *et al.* Identification of Novel Perfluoroalkyl Ether Carboxylic Acids (PFECAs) and Sulfonic Acids (PFESAs) in Natural Waters Using Accurate Mass Time-of-Flight Mass Spectrometry (TOFMS). *Environ Sci Technol* **49**, 11622-11630, doi:10.1021/acs.est.5b01215 (2015).

11 Sun, M. *et al.* Legacy and Emerging Perfluoroalkyl Substances Are Important Drinking Water Contaminants in the Cape Fear River Watershed of North Carolina. *Environmental Science & Technology Letters* **3**, 415-419, doi:10.1021/acs.estlett.6b00398 (2016).

12 Environmental Working Group. *"10 Toxic 'Forever Chemicals' Found in Louisville, Ky., Tap Water"*, <https://www.ewg.org/news-and-analysis/2019/10/10-toxic-forever-chemicals-found-louisville-ky-tap-water> (2019).

13 US EPA. HFPO-DA Results for Public and Private Water Supplies in Vicinity of Chemours Washington Works Facility-February 2018. (2018).

14 Brandsma, S. H., Koekkoek, J. C., van Velzen, M. J. M. & de Boer, J. The PFOA substitute GenX detected in the environment near a fluoropolymer manufacturing plant in the Netherlands. *Chemosphere* **220**, 493-500, doi:10.1016/j.chemosphere.2018.12.135 (2019).

15 Joerss, H. *et al.* Transport of Legacy Perfluoroalkyl Substances and the Replacement Compound HFPO-DA through the Atlantic Gateway to the Arctic Ocean-Is the Arctic a Sink or a Source? *Environ Sci Technol* **54**, 9958-9967, doi:10.1021/acs.est.0c00228 (2020).

16 Nakayama, S. *et al.* Perfluorinated compounds in the Cape Fear Drainage Basin in North Carolina. *Environ Sci Technol* **41**, 5271-5276, doi:10.1021/es070792y (2007).

17 Hopkins, Z. R., Sun, M., DeWitt, J. C. & Knappe, D. R. U. Recently Detected Drinking Water Contaminants: GenX and Other Per- and Polyfluoroalkyl Ether Acids. *Journal AWWA* **110**, 13-28, doi:10.1002/awwa.1073 (2018).

18 McCord, J. & Strynar, M. Identification of Per- and Polyfluoroalkyl Substances in the Cape Fear River by High Resolution Mass Spectrometry and Nontargeted Screening. *Environmental Science & Technology* **53**, 4717-4727, doi:10.1021/acs.est.8b06017 (2019).

19 Kotlarz, N. *et al.* Measurement of Novel, Drinking Water-Associated PFAS in Blood from Adults and Children in Wilmington, North Carolina. *Environmental Health Perspectives* **128**, 077005, doi:doi:10.1289/EHP6837 (2020).
20 Zhang, C., Hopkins, Z. R., McCord, J., Strynar, M. J. & Knappe, D. R. U. Fate of Per- and Polyfluoroalkyl Ether Acids in the Total Oxidizable Precursor Assay and Implications for the Analysis of Impacted Water. *Environ Sci Technol Lett* **6**, 662-668, doi:10.1021/acs.estlett.9b00525 (2019).
21 Chemours. *Consent Order Compliance*, <https://www.chemours.com/en/about-chemours/global-reach/fayetteville-works/compliance-testing> (2020).
22 Geosyntec Consultants. *Characterization of PFAS in Process and Non-Process Wastewater and Stormwater - Quarterly Report #4 - Prepared for The Chemours Company*, <https://www.chemours.com/en/-/media/files/corporate/fayetteville-works/pfas-characterization-quarterly-report_april-2020.pdf> (2020).
23 Geosyntec Consultants. *Chemours Correct Active Plan - Appendix A: Onsite and Offsite Assessment Tables*, <https://files.nc.gov/ncdeq/GenX/consentorder/paragraph-16/FW-CAP-FINAL-12-31-2019-Appendix-A.pdf> (2020).
24 Geosyntec Consultants. *Table 1. PFAS and Associated Methods. Soil sampling results.* , <https://www.chemours.com/en/-/media/files/corporate/11-2-ncdwr-sediment-characterization-plan-updated-table-1-01222020.pdf> (2020).
25 North Carolina Division of Air Quality. *Chemours Company - Fayetteville Works - Air Quality Permit Application Review*, <https://files.nc.gov/ncdeq/Air%20Quality/permits/files/FINAL_AirPermitReview_Chemours_T44_Mar14_with_Appendix_A.pdf> (2019).
26 Food and Drug Administration. *Analytical Results for PFAS in 2018 Produce Sampling (Parts Per Trillion)*, <http://blogs.edf.org/health/files/2019/11/FDA-Analytical-Results-for-PFAS-in-2018-Produce-Sampling-JUNE-2019-with-EDF-NOTES-11-9-19.pdf> (2019).
27 North Carolina Department of Environmental Quality. Consent Order: State of North Carolina and Cape fear River Watch vs. The Chemours Company. (2019).
28 Anonymous. Private well data. Provided by Fayetteville, NC, community member. . (2020).
29 Brunswick County. *Water Test Results - Unregulated Compounds*, <https://www.brunswickcountync.gov/wp-content/uploads/2020/07/6-18-20-0620-750-Final-Report.pdf> (2020).
30 Cape Fear Public Utility Authority. *Raw and Finished PFAS Data: 15 May 2019*, 2019).
31 Cape Fear Public Utility Authority. *Emerging Contaminants*, <https://www.cfpua.org/761/Emerging-Compounds> (2020).
32 Chemours. *Manufacturing Process Polymers Stack E1 Emissions Test Report - 17 May 2018* <https://files.nc.gov/ncdeq/GenX/Data/air-sampling/2018-136ST-Test-Report--Week-of-2018-05-14-.pdf> (2018).
33 Chemours. *Determination of Table 3 Plus Compounds by LC/MS/MS: Chemours Fluoroproducts Analytical Method*, <https://www.chemours.com/en/-/media/files/corporate/table-3-plus-method-consent-order.pdf> (2019).
34 Chemours. *Cover Letter: June 10 2019 - Re: Submission Pursuant to Consent Order Paragraph 11*, <https://www.chemours.com/en/-/media/files/corporate/11-ncdeq-sampling-data-dfsa-2019-06-10.pdf> (2019).
35 H2Go. *Brunswick County PFC Sampling - July 3 2018*, <https://www.h2goonline.com/Images/h2goonline/site/documents/GenX/Test%20Reults/H2GO_Water_Samples_rev__2018-07-03.xlsx> (2018).

36 Chemours. *Analysis of Intake and Captured Process Water - September 2018*, <https://www.chemours.com/Fayetteville-Works/en-us/c3-dimer-acid/compliance-testing/index.html> (2018).
37 Chemours. *Attachment F: Compounds and Potential Compounds in Intake and Outfalls*, 2019).
38 Dong, G. H. *et al.* Chronic effects of perfluorooctanesulfonate exposure on immunotoxicity in adult male C57BL/6 mice. *Arch Toxicol* **83**, 805-815, doi:10.1007/s00204-009-0424-0 (2009).
39 Chemours. PFAS NON-TARGETED ANALYSIS AND METHODS INTERIM REPORT: Process and Non-Process Wastewater and Stormwater (2020).
40 Cordner, A. *et al.* Guideline levels for PFOA and PFOS in drinking water: the role of scientific uncertainty, risk assessment decisions, and social factors. *J Expo Sci Environ Epidemiol* **29**, 157-171, doi:10.1038/s41370-018-0099-9 (2019).
41 US EPA. EPA PFAS Action Plan: Program Update. (2020).
42 Interstate Technology and Regulatory Council (ITRC). *Basis for PFOA and PFOS Values Tables*, <https://pfas-1.itrcweb.org/fact-sheets/> (2020).
43 Temkin, A. M., Hocevar, B. A., Andrews, D. Q., Naidenko, O. V. & Kamendulis, L. M. Application of the Key Characteristics of Carcinogens to Per and Polyfluoroalkyl Substances. *Int J Environ Res Public Health* **17**, doi:10.3390/ijerph17051668 (2020).
44 US EPA. Technical Fact Sheet: Draft Toxicity Assessments for GenX Chemicals and PFBS. (2018).
45 US National Toxicology Program. Toxicology and Carcinogenesis Studies of Perfluorooctanoic Acid Administered in Feed to Sprague Dawley (Hsd:Sprague Dawley SD) Rats. (2020).
46 Nian, M. *et al.* Liver function biomarkers disorder is associated with exposure to perfluoroalkyl acids in adults: Isomers of C8 Health Project in China. *Environ Res* **172**, 81-88, doi:10.1016/j.envres.2019.02.013 (2019).
47 US National Toxicology Program. Immunotoxicity Associated with Exposure to Perfluorooctanoic Acid (PFOA) or Perfluorooctane Sulfonate (PFOS). (2016).
48 US EPA. Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule. (Federal Register 2885, 2890, 2015).
49 Dionisio, K. L. *et al.* The Chemical and Products Database, a resource for exposure-relevant data on chemicals in consumer products. *Sci Data* **5**, 180125, doi:10.1038/sdata.2018.125 (2018).
50 US EPA. *Chemistry Dashboard*, <https://comptox.epa.gov/dashboard> (2020).
51 North Carolina DEQ. Permit NC0089915 to Chemours Fayetteville Works to discharge wastewater under the NPDES. (2020).
52 US EPA. Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3) Also Known as "GenX Chemicals" Report No. EPA Document Number: 823-P-18-001, (2018).
53 Blake, B. E. *et al.* Evaluation of Maternal, Embryo, and Placental Effects in CD-1 Mice following Gestational Exposure to Perfluorooctanoic Acid (PFOA) or Hexafluoropropylene Oxide Dimer Acid (HFPO-DA or GenX). *Environmental Health Perspectives* **128**, 027006, doi:doi:10.1289/EHP6233 (2020).
54 Gomis, M. I., Vestergren, R., Borg, D. & Cousins, I. T. Comparing the toxic potency in vivo of long-chain perfluoroalkyl acids and fluorinated alternatives. *Environ Int* **113**, 1-9, doi:10.1016/j.envint.2018.01.011 (2018).
55 Lau, C. *et al.* Effects of perfluorooctanoic acid exposure during pregnancy in the mouse. *Toxicol Sci* **90**, 510-518, doi:10.1093/toxsci/kfj105 (2006).
56 Zheng, L., Dong, G. H., Jin, Y. H. & He, Q. C. Immunotoxic changes associated with a 7-day oral exposure to perfluorooctanesulfonate (PFOS) in adult male C57BL/6 mice. *Arch Toxicol* **83**, 679-689, doi:10.1007/s00204-008-0361-3 (2009).

57 Patlewicz, G. *et al.* A Chemical Category-Based Prioritization Approach for Selecting 75 Per- and Polyfluoroalkyl Substances (PFAS) for Tiered Toxicity and Toxicokinetic Testing. *Environ Health Perspect* **127**, 14501, doi:10.1289/EHP4555 (2019).
58 Johnson, M. S., Buck, R. C., Cousins, I. T., Weis, C. P. & Fenton, S. E. Estimating Environmental Hazard and Risks from Exposure to Per- and Polyfluoroalkyl Substances (PFASs): Outcome of a SETAC Focused Topic Meeting. *Environ Toxicol Chem*, doi:10.1002/etc.4784 (2020).
59 Steenland, K. *et al.* Review: Evolution of evidence on PFOA and health following the assessments of the C8 Science Panel. *Environ Int* **145**, 106125, doi:10.1016/j.envint.2020.106125 (2020).
60 ATSDR. *Multi-site Health Study - PFAS Cooperative Agreement*, <https://www.atsdr.cdc.gov/pfas/activities/studies/multi-site.html> (2019).
61 Bassler, J. *et al.* Environmental perfluoroalkyl acid exposures are associated with liver disease characterized by apoptosis and altered serum adipocytokines. *Environ Pollut* **247**, 1055-1063, doi:10.1016/j.envpol.2019.01.064 (2019).
62 Liu, G. *et al.* Associations of Perfluoroalkyl substances with blood lipids and Apolipoproteins in lipoprotein subspecies: the POUNDS-lost study. *Environ Health* **19**, 5, doi:10.1186/s12940-020-0561-8 (2020).
63 Zeng, X. W. *et al.* Alternatives of perfluoroalkyl acids and hepatitis B virus surface antibody in adults: Isomers of C8 Health Project in China. *Environmental Pollution* **259**, doi:10.1016/j.envpol.2019.113857 (2020).
64 Grandjean, P. *et al.* Serum vaccine antibody concentrations in children exposed to perfluorinated compounds. *JAMA* **307**, 391-397, doi:10.1001/jama.2011.2034 (2012).
65 Grandjean, P. *et al.* Serum Vaccine Antibody Concentrations in Adolescents Exposed to Perfluorinated Compounds. *Environ Health Perspect* **125**, 077018, doi:10.1289/EHP275 (2017).
66 Tucker, D. K. *et al.* The mammary gland is a sensitive pubertal target in CD-1 and C57Bl/6 mice following perinatal perfluorooctanoic acid (PFOA) exposure. *Reprod Toxicol* **54**, 26-36, doi:10.1016/j.reprotox.2014.12.002 (2015).
67 White, S. S. *et al.* Gestational and chronic low-dose PFOA exposures and mammary gland growth and differentiation in three generations of CD-1 mice. *Environ Health Perspect* **119**, 1070-1076, doi:10.1289/ehp.1002741 (2011).
68 Hill, P., Carper, Bee & Deitzler, PLLC. *The Brookmar C8 Health Project (CO)*, <https://www.hpcbd.com/Personal-Injury/DuPont-C8/The-Brookmar-C8-Health-Project-CO.shtml> (2020).
69 Emmett, E. A. *et al.* Community exposure to perfluorooctanoate: relationships between serum levels and certain health parameters. *J Occup Environ Med* **48**, 771-779, doi:10.1097/01.jom.0000233380.13087.37 (2006).
70 Nolan, L. A., Nolan, J. M., Shofer, F. S., Rodway, N. V. & Emmett, E. A. The relationship between birth weight, gestational age and perfluorooctanoic acid (PFOA)-contaminated public drinking water. *Reprod Toxicol* **27**, 231-238, doi:10.1016/j.reprotox.2008.11.001 (2009).
71 Waterfield, G., Rogers, M., Grandjean, P., Auffhammer, M. & Sunding, D. Reducing exposure to high levels of perfluorinated compounds in drinking water improves reproductive outcomes: evidence from an intervention in Minnesota. *Environ Health* (2020).
72 US EPA. C.I. Pigment Violet 29 (Anthra[2, 1,9-def:6,5, 1 Od'e'f']diisoquinoline-1 ,3,8, 10(2H,9H)-tetrone) TSCA Section 4 Test Order (Docket ID Number: EPA-HQ-OPPT-2020-0070). (2020).
73 Foster, P. M. Influence of Study Design on Developmental and Reproductive Toxicology Study Outcomes. *Toxicol Pathol* **45**, 107-113, doi:10.1177/0192623316671608 (2017).

ATTACHMENT 1

ATTACHMENT B

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 7, 2021

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

Robert M. Sussman
Sussman and Associates
3101 Garfield Street, NW
Washington DC 20008
bobsussman1@comcast.net

Dear Mr. Sussman:

The U.S. Environmental Protection Agency (EPA) is responding to the petition filed pursuant to section 21 of the Toxic Substances Control Act (TSCA), received on October 14, 2020, from you as counsel for the following petitioners: Center for Environmental Health, Cape Fear River Watch, Clean Cape Fear, Democracy Green, Toxic Free NC and the NC Black Alliance – pursuant to Section 21 of the Toxic Substances Control Act (TSCA). The petition "requests that [EPA] require health and environmental effects testing on 54 Per- and Polyfluoroalkyl Substances (PFAS) manufactured by The Chemours Company (Chemours) at its chemical production facility in Fayetteville, North Carolina." The petition also "seeks issuance of a rule or order under Section 4 of TSCA compelling Chemours to fund and carry out this testing under the direction of a panel of independent scientists."

EPA has reviewed the information submitted in your petition. Based on this review and after careful consideration of your specific requests, EPA is denying the petition. The Agency's reasons for denying your petition are enumerated in the enclosed pre-publication copy of the notice of denial that has been submitted for publication in a forthcoming edition of the **Federal Register**.

Under TSCA section 21, the petitioners have the right to appeal the Agency's denial of its petition by commencing a civil action in a U.S. district court to compel initiation of the requested proceeding within 60 days of a denial. If you would like to discuss this matter further, please contact Tala Henry, Deputy Director of the Office of Pollution Prevention and Toxics, at 202-564-2959 or by email at henry.tala@epa.gov.

Sincerely,

ALEXANDRA DAPOLITO DUNN

Digitally signed by ALEXANDRA DAPOLITO DUNN
Date: 2021.01.07 12:23:27 -05'00'

Alexandra Dapolito Dunn, Esq.
Assistant Administrator

Enclosures

This page is intentionally blank.

PRE-PUBLICATION NOTICE

On January 7, 2021, **Alexandra Dapolito Dunn**, the EPA Assistant Administrator for the Office of Chemical Safety and Pollution Prevention, signed the following document:

Action: Notice
Title: **TSCA Section 21 Petition for Rulemaking; Reasons for Agency Response; Denial of Requested Rulemaking**
FRL #: 10019-39
Docket ID #: EPA-HQ-OPPT-2020-0565

EPA is submitting this document for publication in the *Federal Register* (FR). EPA is providing this document solely for the convenience of interested parties. It is not the official version of the document for purposes of public notice and comment under the Administrative Procedure Act. This document is not disseminated for purposes of EPA's Information Quality Guidelines and does not represent an Agency determination or policy. While we have taken steps to ensure the accuracy of this Internet version of the document that was signed, the official version will publish in a forthcoming FR publication, which will appear on the Government Printing Office's govinfo website (https://www.govinfo.gov/app/collection/fr) and on Regulations.gov (https://www.regulations.gov) in the docket identified above.

Once the official version of this document is published in the *Federal Register*, this version will be removed from the Internet and replaced with a link to the official version. At that time, you will also be able to access the on-line docket for this *Federal Register* document at http://www.regulations.gov.

For further information about the docket and, if applicable, instructions for commenting, please consult the ADDRESSES section in the front of the Federal Register document.

This page is intentionally blank.

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Chapter I

[EPA-HQ-OPPT-2020-0565; FRL-10019-39]

TSCA Section 21 Petition for Rulemaking; Reasons for Agency Response; Denial of Requested Rulemaking

AGENCY: Environmental Protection Agency (EPA).

ACTION: Petition; reasons for Agency response.

SUMMARY: This document provides the reasons for the Environmental Protection Agency's (EPA's) response to a petition it received under the Toxic Substances Control Act (TSCA) from the Center for Environmental Health, Cape Fear River Watch, Clean Cape Fear, Democracy Green, Toxic Free NC, and the NC Black Alliance on October 14, 2020. Generally, the petitioners requested that EPA initiate a rulemaking proceeding or issue an order under TSCA compelling health and environmental effects testing on 54 Per- and Polyfluoroalkyl Substances (PFAS) that the petitioners assert are manufactured by The Chemours Company (Chemours) at its chemical production facility in Fayetteville, North Carolina. The petitioners also request that EPA ask the National Academy of Sciences to create an independent science panel to oversee all aspects of the testing program requested by the petitioners. After careful consideration, EPA denied the TSCA petition for reasons discussed in this document.

DATES: EPA's response to this TSCA section 21 petition was signed January 7, 2021.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2020-0565, is available online at *https://www.regulations.gov* or in-person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection

Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Public Reading Room are closed to visitors with limited exceptions. The EPA/DC staff continue to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Daniel R. Ruedy, Data Gathering and Analysis Division (7410M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-7974; email address: *ruedy.daniel@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action, however, may be of particular interest to those persons who manufacture (which includes import), distribute in commerce, process, use, or dispose of one or more of the 54 Per- and Polyfluoroalkyl Substances (PFAS) identified in the petition. Since other entities may also be interested, the Agency has not

attempted to describe all the specific entities that may be affected by this action.

B. What is EPA's authority for taking this action?

Under TSCA section 21 (15 U.S.C. 2620), any person can petition EPA to initiate a proceeding for the issuance, amendment, or repeal of a rule under TSCA sections 4, 6, or 8, or to issue an order under TSCA sections 4, 5(e), or 5(f). A TSCA section 21 petition must set forth the facts which it is claimed establish that it is necessary to initiate the action requested. EPA is required to grant or deny the petition within 90 days of its filing. If EPA grants the petition, the Agency must promptly commence an appropriate proceeding. If EPA denies the petition, the Agency must publish its reasons for the denial in the Federal Register. A petitioner may commence a civil action in a U.S. district court seeking to compel initiation of the requested proceeding within 60 days of a denial or, if EPA does not issue a decision, within 60 days of the expiration of the 90-day period.

C. What criteria apply to a decision on a TSCA section 21 petition?

1. Legal standard regarding TSCA section 21 petitions.

TSCA section 21(b)(1) requires that the petition "set forth the facts which it is claimed establish that it is necessary" to initiate the proceeding requested. 15 U.S.C. 2620(b)(1). Thus, TSCA section 21 implicitly incorporates the statutory standards that apply to the requested actions. Accordingly, EPA has relied on the standards in TSCA section 21 and in the provisions under which actions have been requested in evaluating this TSCA section 21 petition.

2. Legal standard regarding TSCA section 4(a)(1)(A)(i).

EPA must make several findings in order to require testing under TSCA section 4(a)(1)(A)(i) through a rule or order. EPA must find that the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any

combination of such activities, may present an unreasonable risk of injury to health or the environment; that information and experience are insufficient to reasonably determine or predict the effects of a chemical substance on health or the environment; and that testing of the chemical substance is necessary to develop the missing information. Further, TSCA section 4(h) requires EPA to reduce and replace the use of vertebrate animals in the testing of chemical substances or mixtures, to the extent practicable, scientifically justified, and consistent with the policies of TSCA.

3. Legal standard regarding TSCA section 26.

TSCA section 26(h) requires EPA, in carrying out TSCA sections 4, 5, and 6, to make a decision using "scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science," while also taking into account six considerations, including the relevance of information and any uncertainties. TSCA section 26(i) requires that decisions under TSCA sections 4, 5, and 6 be "based on the weight of scientific evidence." TSCA section 26(k) requires that EPA consider information that is reasonably available in carrying out TSCA sections 4, 5, and 6.

II. Summary of the TSCA Section 21 Petition

A. What action was requested?

On October 14, 2020, Center for Environmental Health, Cape Fear River Watch, Clean Cape Fear, Democracy Green, Toxic Free NC, and the NC Black Alliance (petitioners) petitioned EPA to initiate a rulemaking proceeding or issue an order under TSCA section 4(a)(1)(A)(i), compelling health and environmental effects testing, including studies of communities exposed to PFAS-contaminated drinking water, on 54 PFAS that the petitioners assert are manufactured by The Chemours Company (Chemours) at its chemical production facility in Fayetteville, North

Carolina. The petitioners also request that EPA ask the National Academy of Sciences to create an independent science panel to oversee all aspects of the testing program requested by the petitioners (Ref. 1).

B. What support did the petitioners offer?

The petitioners assert that TSCA section 4(a)(1)(A)(i) requires EPA to direct testing on a chemical substance or mixture if all three of the following findings are made:

• The manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment;

• There is insufficient information and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted; and

• Testing of such substance or mixture with respect to such effects is necessary to develop such information.

1. May present an unreasonable risk of injury to health or the environment.

The petitioners assert that the 54 PFAS "may present an unreasonable risk of injury to health or the environment" because there allegedly is substantial evidence that PFAS may be toxic, pointing to the following documents:

• The Agency for Toxic Substances and Disease Registry's (ATSDR's) draft 2018 Toxicological Profile for Perfluoroalkyls (Ref. 2) and EPA's PFAS Action Plan (Ref. 3), as well as other literature, in support of the contention that exposure to certain, specific PFAS are associated with adverse health effects.

• EPA's Significant New Use Rule (SNUR) for Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances (Ref. 4), which states "[w]hile most studies to date have focused primarily on PFOS, structure-activity relationship analysis indicates that the results of those studies are applicable to the entire category of PFAS, which includes PFOS. Available test data have raised concerns about their potential developmental, reproductive, and systemic toxicity."

• EPA's Consent Order regarding DuPont Premanufacture Notices (Ref. 5), which states in part "[t]oxicity studies on the analogs PFOA (perfluorooctanoic acid) and PFOS (perfluorooctanesulfonic acid) indicate developmental, reproductive and systemic toxicity in various species. Cancer may also be of concern. These factors, taken together, raise concerns for potential adverse chronic effects in humans and wildlife."

The petitioners conclude, based on the references provided, that "all PFAS have the potential for causing the adverse health and environmental effects linked to well-characterized substances like PFOS and PFOA because of their common structural characteristics," and that "there is a strong basis to conclude that the 54 PFAS covered by this petition 'may present an unreasonable risk of injury'" (Ref. 1, pg. 18).

2. Insufficiency of information.

The petitioners assert that for these 54 PFAS, there is insufficient information and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted. To support their assertion, the petitioners point to:

• ATSDR's draft 2018 Toxicological Profile for Perfluoroalkyls (Ref. 2), which the

petitioners assert underscores the absence of toxicological data; and

• EPA's PFAS Action Plan (Ref. 3), which states "[t]here are many PFAS of potential concern to the public that may be found in the environment. Most of these PFAS lack sufficient toxicity data to inform our understanding of the potential for adverse human or ecological effects."

On page 21 of their petition, the petitioners assert: "[k]ey data gaps include measurement of physical-chemical properties, methods of analysis, assessment of partitioning, bioaccumulation, and degradation, pharmacokinetics, and toxicity, especially for the endpoints commonly observed for the better studied PFAS, such as liver toxicity, and effects on the immune system, lipid metabolism, kidney, thyroid, development, reproduction, and cancer. In addition, despite their widespread detection in environmental media, ecotoxicity data are generally lacking."

3. Need for testing.

The petitioners assert that the mechanisms of PFAS toxic effects are not defined, and that in vitro assays or other predictive, computational approaches are not validated or available. The petitioners also request animal toxicity studies on three mixtures of PFAS that are allegedly representative of exposure for residents in the Cape Fear Watershed.

Finally, the petitioners request ecotoxicity studies, and studies of physical chemical properties and environmental fate and transport, which they say EPA "has previously determined are necessary because of the widespread presence and mobility of PFAS in environmental media."

4. Testing framework and specific studies.

The petitioners propose a testing approach that they call for Chemours to perform. The

list of 54 PFAS was divided into Tier 1 substances for which there is "known human exposure based on detection in blood, food, or drinking water," and Tier 2 substances for which "human exposure is probable based on detection in environmental media" (Ref. 1, pg.12). The testing approach includes human health effects studies in experimental animals, animal studies on PFAS mixtures, studies of communities exposed to PFAS-contaminated drinking water, human half-life studies, physical-chemical properties and fate and transport studies, and ecotoxicity testing.

III. Background Considerations: Review of EPA Actions, Activities, and Regulations Relating to PFAS

To understand EPA's reasons for denying the petitioners' requests, it is important to first review the details of EPA's ongoing actions involving PFAS. EPA is committed to supporting states, tribes, and local communities in addressing challenges with PFAS. As a part of this effort, EPA is already taking action to identify solutions to address PFAS in the environment. Examples of such ongoing actions are detailed in this unit.

A. PFAS Action Plan: Program Update

In May 2018, EPA convened a two-day National Leadership Summit on PFAS that brought together more than 200 federal, state, and local leaders to discuss steps to address PFAS. The Summit set the following goals: evaluate the need for a maximum contaminant level for PFOA and PFOS in drinking water, evaluate designating PFOA and PFOS as hazardous substances, issue groundwater cleanup guidances for PFOA and PFOS, and develop toxicity values for GenX and perfluorobutane sulfonic acid (PFBS). Following the Summit, EPA interacted with more than 1,000 people during PFAS-focused community engagement events in Exeter, New Hampshire; Horsham, Pennsylvania; Colorado Springs, Colorado; Fayetteville, North Carolina; and Leavenworth, Kansas, as well as through a roundtable in Kalamazoo,

Michigan, and an event with tribal representatives in Spokane, Washington. As a result of these meetings and building on the goals identified at the Summit and the approximately 120,000 public comments received by the agency, EPA developed the PFAS Action Plan, which was issued in February 2019 (Ref. 3).

The PFAS Action Plan is the first multi-media, multi-program, national research, management, and risk communication plan to address an emerging contaminant like PFAS. The PFAS Action Plan outlines the tools EPA is developing to, among other things, address PFAS in drinking water, identify and clean up PFAS contamination, expand monitoring of PFAS, increase PFAS scientific research, and exercise effective enforcement tools. The Action Plan outlines EPA's commitment to take a wide variety of actions to address this emerging contaminant in both short-term and long-term timeframes. Together, these efforts are helping EPA and its partners identify and better understand PFAS contaminants generally, clean up current PFAS contamination, prevent future contamination, and effectively communicate risk with the public. In February 2020, EPA issued the *PFAS Action Plan: Program Update* (available at *https://www.epa.gov/pfas/pfas-action-plan-program-update-february-2020*) to provide an update on all of the actions taken and work completed in the year since the PFAS Action Plan was issued. As it continues to implement the PFAS Action Plan, EPA is committed to coordinating closely with multiple entities, including other federal agencies, states, tribes, local governments, water utilities, industry, and the public.

B. Interim Strategy for PFAS in Federally Issued National Pollutant Discharge Elimination System (NPDES) Permits

EPA's Office of Water (OW) is currently leading multiple actions in the PFAS Action Plan that will help the Agency better understand and effectively manage risk from exposure to

PFAS. These OW-led actions include developing analytical methods for detecting PFAS in drinking water and other environmental media, evaluating PFAS treatment techniques, conducting data collection and analysis to evaluate the need for regulations to control PFAS discharges from certain categories of point sources, understanding PFAS exposure from various environmental media, and evaluating statutory and regulatory mechanisms to manage adverse human health and environmental impacts from PFAS exposure.

While OW's work is advancing, a need for an interim strategy to address point source discharges of PFAS in EPA-issued NPDES permits was identified. On February 6, 2020, a workgroup was established to develop an interim NPDES permitting strategy to address PFAS in EPA-issued CWA section 402 permits. The workgroup was charged with exploring options for how to address these pollutants while the CWA framework for addressing PFAS discharges pursuant to the NPDES program is under development. The workgroup's goal was to develop a strategy that would serve to guide the Agency's CWA NPDES permitting approach on an interim basis across the EPA Regions as informed by input from state partners. Each of the ten EPA Regions appointed a representative to the workgroup.

To develop potential recommendations for an interim PFAS NPDES strategy, the workgroup conducted a thorough review of the NPDES permitting process, with a specific focus on PFAS. This included examining CWA section 402 authorities and permit writing practices to understand where unregulated contaminants, such as PFAS, may fit into the permit development process; analyzing existing state-issued NPDES permits with PFAS monitoring requirements (identified through EPA's NPDES Integrated Compliance Information System (ICIS)) to understand the prescribed analytical methods for detecting PFAS, monitoring frequency, and detection benchmarks in current permits; and obtaining input and perspectives from state

partners. In November 2020, EPA issued a memo detailing an interim NPDES permitting strategy for PFAS. This strategy is being implemented for EPA-issued NPDES permits.

C. Workshop on Federal Government Human Health PFAS Research with the National Academies of Sciences, Engineering and Medicine

On October 26-27, 2020, the National Academies of Science, Engineering, and Medicine (NASEM) held a Workshop on Federal Government Human Health PFAS Research. This workshop was the result of collaboration between EPA, the U.S. Department of Defense (DoD), the U.S. Department of Agriculture (USDA), and the U.S. Department of Health and Human Services (HHS) and will help further coordinate PFAS research across the federal government. Aggressively addressing PFAS has been an active and ongoing priority for this Administration, and the goal of the workshop was to discuss ongoing federal research and data gaps. Following the workshop, NASEM will compile a report summarizing the discussion and views of workshop participants on how to ensure that the federal research program for PFAS is robust and focused on addressing the highest priority human health research. Workshop proceedings will be published in early 2021.

D. Safe Drinking Water Act (SDWA) Actions for PFOA and PFOS

EPA has taken a number of actions under SDWA, consistent with the PFAS Action Plan and its statutory and regulatory authorities. In 2016, EPA established health advisories for PFOA and PFOS (Ref. 6) based on the Agency's assessment of the latest peer-reviewed science to provide drinking water system operators, and state, tribal and local officials who have the primary responsibility for overseeing these systems, with information on the health risks of these chemicals, so they can take the appropriate actions to protect their residents. To provide Americans, including the most sensitive populations, with a margin of protection from a lifetime

of exposure to PFOA and PFOS from drinking water, EPA established the health advisory levels at 70 parts per trillion.

EPA is committed to following the regulatory process established under SDWA and supporting states and public water systems as they determine the appropriate steps to reduce exposure to PFOA and PFOS in drinking water.

E. National Primary Drinking Water Regulation for PFOA and PFOS

On March 10, 2020, EPA published a notice (85 FR 14098, FRL-10005-88) seeking comment on proposed determinations to regulate PFOA and PFOS. EPA is considering the public comments on this notice and expects to issue final regulatory determination in January 2021. If EPA issues final determinations to regulate PFOA and PFOS, SDWA requires that the EPA publish a proposed regulation within 24 months of the final determination and promulgate a final regulation within 18 months of proposal (SDWA allows the Agency to extend that final rule deadline by 9 months).

Under the third Unregulated Contaminant Monitoring Rule (UCMR 3) (85 FR 26072, FRL-9660-4), from 2013 to 2015, EPA required almost 5,000 public water systems to monitor for six PFAS (see *https://www.epa.gov/dwucmr/third-unregulated-contaminant-monitoring-rule*). The results of this monitoring were used by EPA in making the proposed regulatory determination for PFOA and PFOS. EPA has committed to monitoring for more PFAS in the UCMR 5 and at lower levels than was possible under the UCMR 3. EPA expects to publish a proposed UCMR 5 in January 2021.

F. PFOA Stewardship Program

EPA launched the PFOA Stewardship Program (Ref. 7) in January, 2006 because of concerns about the impact of PFOA and long-chain PFAS on human health and the environment,

including concerns about their persistence, presence in the environment and in the blood of the general U.S. population, long half-life in people, and developmental and other adverse effects in laboratory animals.

By March 1, 2006, the eight major companies in the PFAS industry submitted commitments to the PFOA Stewardship Program. Specifically, these companies committed to reducing PFOA from facility emissions and product content by 95 percent no later than 2010, and to work toward eliminating PFOA from emissions and product content no later than 2015. The companies participating in the PFOA Stewardship Program were global companies with business operations in the United States and other countries.

To meet the program goals, most companies stopped the manufacture and import of long-chain PFAS, and then transitioned to alternative chemicals. Other companies exited the PFAS industry altogether. All participating companies state that they met the PFOA Stewardship Program goals. In July 2020 EPA codified and expanded the impact of the PFOA Stewardship program through the issuance of the long chain PFAS SNUR, as discussed in Unit III.H.

G. Addition of Certain PFAS to the Toxics Release Inventory (TRI) Regulations

The National Defense Authorization Act for Fiscal Year 2020 (NDAA) (Pub. L. 116-92) added certain PFAS to the list of chemicals required to be reported to the TRI and established a 100-pound reporting threshold for these substances. EPA's TRI is an important tool that provides the public with information about the use of certain chemicals by tracking their management and associated activities. U.S. facilities in different industry sectors must report annually how much of each chemical is released to the environment and/or managed through recycling, energy recovery, and treatment. TRI helps support informed decision-making by companies, government agencies, non-governmental organizations and the public. For example, EPA uses

TRI information to understand releases and potential exposures to chemicals being assessed under TSCA.

In June 2020, the Agency published a final rule (85 FR 37354, June 22, 2020; FRL-10008-09) that updated the regulations to reflect the addition of these PFAS to the TRI by the NDAA. Per the NDAA requirements, the PFAS additions became effective as of January 1, 2020. Reporting for these PFAS will be due to EPA by July 1, 2021, for calendar year 2020 data. By July 31, 2021, EPA expects to release raw data concerning the TRI-listed PFAS from information collected. Additionally, the NDAA provides a framework for additional PFAS to be added automatically to the TRI list on January 1 of the year following certain EPA actions (NDAA section 7321(c)). For example, the NDAA automatically adds a PFAS to the TRI list in response to the EPA finalizing a toxicity value for it.

H. Regulatory Actions Under TSCA

EPA has taken a range of regulatory actions under TSCA to address potential exposures and/or risks associated with manufacturing, processing, and use of PFAS. EPA's New Chemicals program reviews alternatives for PFOA and related chemicals before they enter the marketplace to identify whether the range of toxicity, fate and bioaccumulation issues that have caused past concerns with perfluorinated substances may be present in order to ensure that the new chemicals do not present an unreasonable risk to health or the environment.

TSCA Section 5(a) SNURs can be used to require notice to EPA before chemical substances and mixtures are used in new ways that might create concerns. Under TSCA section 5(a), EPA can determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2):

• Projected volume of manufacturing and processing of a chemical substance.

• Extent to which a use changes the type or form of exposure of humans or the environment to a chemical substance.

• Extent to which a use increases the magnitude and duration of exposure of humans or the environment to a chemical substance.

• Reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

Once EPA designates a use of a chemical substance as a significant new use, TSCA section 5(a) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture (including import) or process the chemical substance for that use. The SNUN obligates EPA to assess risks that may be associated with that significant new use, including risks to potentially exposed or susceptible subpopulations identified as relevant by EPA under the conditions of use; make a determination under the statute; and, if appropriate, regulate the proposed activity before it occurs.

EPA has issued the following SNURs for PFOS and PFAS:

• On March 11, 2002, EPA issued a final SNUR (Ref. 8) for 13 PFAS specifically included in the voluntary phase out of PFOS by 3M that took place between 2000 and 2002.

• On December 9, 2002, EPA issued a final SNUR (Ref. 9) for 75 PFAS specifically included in the voluntary phase out of PFOS by 3M that took place between 2000 and 2002.

• On October 9, 2007, EPA issued a final SNUR (Ref. 10) for 183 PFAS that were on the public TSCA Inventory and have the characteristic PFAS chemical structure of a perfluorinated carbon chain (Rf) greater than, or equal to, C5 attached to an SO2 group connected to the rest of the molecule. In addition, the proposal also included those chemicals with Rf ranges of

perfluorinated carbon chains shorter than C5, and greater than C5, for example, C4-C12 and C6-C12.

• On October 22, 2013, EPA issued a final SNUR (Ref. 11) for certain PFOA-related chemicals as part of carpets, a category of potentially harmful chemicals once used on carpets to impart soil, water, and stain resistance.

• On July 27, 2020, EPA issued a final SNUR (Ref. 12) for certain PFOA-related chemicals. The SNUR modifies the requirements for a subset of LCPFAC chemical substances in the existing SNUR at 40 CFR 721.10536 in the following ways: 1) Designating manufacturing (including importing) or processing of LCPFAC chemical substances listed in the list of LCPFAC chemical substances for any use that was no longer ongoing after December 31, 2015, as a significant new use; and 2) Designating manufacturing (including importing) or processing of PFOA or its salts, which are considered LCPFAC chemical substances, and all other LCPFAC chemical substances for any use not ongoing as of January 21, 2015, the date on which the proposed rule was published, as a significant new use. For this final SNUR, EPA also made an exemption at 40 CFR 721.45(f) inapplicable for persons who import LCPFAC chemical substances listed in the list of LCPFAC chemical substances in this unit and PFOA or its salts as part of a surface coating on articles because there is reasonable potential for exposure to LCPFAC chemical substances, including PFOA, if these chemical substances are incorporated as surface coatings in articles and then imported.

In addition, in December 2020, EPA issued draft guidance (Ref. 13) for public comment outlining which imported articles are covered by the July 2020 final rule for certain long-chain PFAS. After considering comments, EPA intends to issue the final guidance promptly.

PFOS was not reported as manufactured (including imported) into the United States as

part of the 2012 Chemical Data Reporting (CDR) effort or the previous collection effort in 2006. CDR requires manufacturers (including importers) to report if they meet certain production volume thresholds, generally 25,000 lbs at a single site. The last time PFOS manufacture was reported to EPA as part of this collection effort was 2002; nonetheless, there are some limited ongoing uses of PFOS (see 40 CFR 721.9582).

I. Increasing Research and Understanding PFAS

Building on the work outlined in the February 2019 PFAS Action Plan, the Agency expanded its research efforts and capabilities by launching the PFAS Innovative Treatment Team (PITT) in spring 2020. The PITT was a full-time, multi-disciplinary research team that concentrated their efforts and expertise on a single problem for six months: how to remove, destroy, and test PFAS-contaminated media and waste. The PITT's goals were to:

• Assess current and emerging destruction methods being explored by EPA, universities, other research organizations, and industry;

• Explore the efficacy of destruction methods while considering by-products to avoid creating new environmental hazards; and

• Evaluate destruction methods' feasibility, performance, and costs to validate potential solutions.

This work initiated under the PITT will add practical knowledge to EPA's efforts under the PFAS Action Plan. States, tribes, and local governments will be able to use this information to select the approach that best fits their circumstances, leading to greater confidence in cleanup operations and safer communities.

Besides the innovative work of PITT, EPA and its researchers continue to work hard in many other areas to help the nation address PFAS and protect public health. This work includes:

• Validating methods to detect and quantify PFAS in various environmental media, such as water, air, and biosolids. EPA has already released a number of these methods, including Methods 533 and 537.1 that together can measure 29 PFAS in drinking water;

• Evaluating treatment technologies that remove PFAS from drinking water. For example, researchers are investigating the effectiveness of point-of-use systems and have recently published research on commercially available systems that use both reverse osmosis and granular activated carbon;

• Developing standard human health toxicity reference values for certain PFAS. For example, Agency scientists are working on a toxicity assessment for PFBS, GenX chemicals, and five other PFAS that will help states, tribes, and local communities understand the toxicity of these substances so that they can make more informed choices to protect the public's health;

• Providing technical assistance to states and tribes as they work to address a variety of PFAS challenges; and

• Funding external researchers to better understand the potential impacts of PFAS on water quality and availability in rural communities and agricultural operations across the United States.

IV. Disposition of TSCA Section 21 Petition

A. What was EPA's response?

After careful consideration, EPA has denied the petition. A copy of the Agency's response, which consists of the letter to the petitioners and this document, is psoted on the EPA petition website at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-21#reporting*. The response, the petition (Ref. 1) and other information is available in the docket for this TSCA section 21 petition (see **ADDRESSES)**.

The denial is not based on lack of concern with PFAS. In fact, EPA's high concern for these chemicals is detailed in Unit III. of this document. EPA is leading the national efforts to understand PFAS and reduce PFAS risks to the public through implementation of its PFAS Action Plan and through active engagement and partnership with other federal agencies, states, tribes, industry groups, associations, local communities, and the public. Instead, EPA finds the petitioners have not met their burden under TSCA section 21, as explained in Unit IV.B. of this document.

B. What was EPA's reason for this response?

In considering the petition within the statutory 90-day petition review period, EPA evaluated the information presented or referenced in the petition and considered that information in the context of the applicable authorities and requirements contained in TSCA sections 4, 21, and 26. Also, notwithstanding that the burden is on the petitioners to present "the facts which it is claimed establish that it is necessary" for EPA to initiate the rule or issue the order sought, EPA nonetheless also evaluated relevant information that was reasonably available to the Agency during the 90-day petition review period.

As detailed extensively in the units that follow, EPA finds the petitioners have not provided the facts necessary for the Agency to determine for each of the 54 PFAS that existing information and experience are insufficient and testing of such substance or mixture with respect to such effects is necessary to develop such information. These deficiencies, among other findings, are detailed in this document.

1. Insufficient information and experience.

The petition does not set forth the facts necessary to demonstrate that there is "insufficient information and experience" for each of the 54 PFAS. The petitioners state, in part,

"[f]or the 54 PFAS, the sufficiency of available information should be determined by comparing available data with the known adverse effects of other PFAS. The goal should be to conduct a scientifically sound assessment of each of the 54 chemicals for the critical toxic endpoints that have been identified in studies on PFOS, PFOA and other well-characterized studies" (Ref. 1, pg. 21). However, the petitioners do not provide evidence that they conducted an assessment to support a finding of insufficient information and experience.

The petitioners instead point to broad statements in the EPA PFAS Action Plan, such as "[t]here are many PFAS of potential concern to the public that may be found in the environment. Most of these PFAS lack sufficient toxicity data to inform our understanding of the potential for adverse human or ecological effects" (Ref. 3, pg. 31). The petitioners base the fate and transport studies they request on EPA's PFAS Action Plan, which the petitioners quote as stating "information for many PFAS sources, fate and transport, and human and ecological exposure is sparse, both spatially and temporally" (Ref. 3, pg. 31). However, the PFAS Action Plan broadly states only that such information for "many PFAS sources" is sparse; nowhere does it state or conclude that such information is sparse for each of the 54 PFAS the petitioners identify.

To further demonstrate that the information and experience on the 54 PFAS is allegedly insufficient, the petitioners cite ATSDR's 2018 Toxicological Profile for perfluoroalkyls, which the petitioners acknowledge "identifies numerous critical data gaps for PFAS ***as a class***" (emphasis added). The ATSDR 2018 Toxicological Profile for perfluoroalkyls remains in draft form and discusses information on 14 perfluoroalkyl compounds, none of which are among the 54 the petitioners identify. Importantly, the ATSDR 2018 Toxicological Profile further states that "[t]he term 'perfluoroalkyls' used throughout the toxicological profile is referring to these 14 compounds and the information may not be applicable to other perfluoroalkyl compounds" (Ref.

2, pg. 1). Despite this qualifying statement, the petitioners proceed to state without reference or additional explanation that "[t]he 54 substances covered by this petition fit this pattern" (Ref. 1, pg. 21). This extrapolation is fundamentally important to the petitioners' argument, yet there are no facts in the petition to support the statement. The petitioners are not clear as to what "pattern" the 54 PFAS fit, and no other sources are provided.

Absent any factual support in the petition, EPA finds that mere reference to these broad statements from the EPA PFAS Action Plan and ATSDR's 2018 Toxicological Profile for perfluoroalkyls does not provide the facts necessary for the Agency to determine there is insufficient information or experience for these 54 PFAS.

To further characterize this baseline deficiency, EPA performed a cursory search of public literature and databases for reasonably available information on any of the 54 PFAS identified by the petitioners. Representative findings of this cursory review are summarized as follows:

• On June 8, 1987, EPA issued a Final Test Rule for Fluoroalkenes (Ref. 14) requiring testing for certain health effects for four fluoroalkenes, two of which are among the 54 PFAS the petitioners identify: hexafluoropropylene (CAS No. 116-15-4) and tetrafluoroethylene (CAS No. 116-14-3). The petitioners do not identify this test rule and the testing it required, nor do the petitioners explore and explain why the testing the rule ordered did not generate the health effects data the petitioners are now requesting.

• EPA's web-based CompTox Chemistry Dashboard integrates various types of data for curated substances linked to chemical structures, including physicochemical, environmental fate and transport, exposure, usage, in vivo toxicity, and in vitro bioassay data (Ref. 15). A query for some of the 54 PFAS in CompTox returned physical/chemical property and hazard data. For

example, CompTox has published experimental averages for melting point, boiling point, water solubility, and vapor pressure, and some hazard data and sources for tetrafluoroethylene (CAS No. 116-14-3). CompTox also has published some hazard data for hexafluoropropylene (CAS No. 116-15-4) and perflouromethylperfluorovinyl ether (CAS No. 1187-93-5). Finally, some physical/chemical data for perfluoro (4-methyl-3, 6- dioxaoct-7-ene) sulfonyl fluoride (CAS No. 16090-14-5) are also readily available. The petitioners mention none of these data, nor have they provided the facts necessary to show that the information in CompTox is insufficient.

• ChemView provides the public access to reports and dataset information including data submitted to EPA, EPA Assessments and Actions, and data provided by other EPA Offices and federal organizations (Ref. 16). A query for each of the 54 PFAS in ChemView returned records for 17 of the 54 PFAS. For example, for perflouromethylperfluorovinyl ether (CAS No. 1187-93-5), a substantial risk report is available from DuPont Haskell Global Centers on reproduction/developmental toxicity screening tests (OECD 422/OPPTS 870.3650, one of the methods identified in the petitioners' testing program) in rats (Ref. 17). The petitioners do not mention this report, nor do they explain why the report fails to provide the data being sought. In this way, the petitioners once again have not provided the facts necessary to show that the information in ChemView is insufficient.

• Tetrafluoroethylene (CAS No. 116-14-3) is pre-registered under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation. The European Chemicals Agency (ECHA) has compiled chemical/physical property data (partition coefficient, potential for bioaccumulation, etc.) for this PFAS. Hexafluoropropylene (CAS No. 116-15-4) is also pre-registered under REACH, and ECHA has compiled some chemical/physical property data for this PFAS. The petitioners mention none of these data, nor have they provided the facts

necessary to show that this information is insufficient.

TSCA section 21 requires the petitioner, not EPA, to "set forth the facts which it is claimed establish that it is necessary to issue, amend, or repeal a rule under TSCA sections 4, 6, or 8, or an order under TSCA sections 4 or 5(e)." Because EPA, upon a cursory review, has been able to easily identify existing, reasonably available information not mentioned in the petition, the petitioners have failed in carrying their burden of setting forth facts which are necessary to demonstrate that there is insufficient information, thereby necessitating the requested action.

For one of the 54 PFAS, identified only as N1AF, the petitioners provide no structurally-descriptive chemical name, structure, or molecular formula. Absent such identifying information, the petitioners have not provided the facts necessary to determine whether there is "insufficient information or experience" for this chemical.

Because the petitioners are seeking tests for each of the 54 PFAS, the petitioners must set forth facts that establish it is necessary to pursue the rule or issue the order the petitioners seek under TSCA section 4. The petitioners must affirmatively demonstrate, through facts, that there is "insufficient information and experience" for each of the 54 PFAS. For the reasons described in this document, EPA finds the petition does not set forth facts necessary to demonstrate "insufficient information and experience" for each of the 54 PFAS, and has therefore not demonstrated that the rule or order requested is necessary.

2. Testing of such substance or mixture with respect to such effects is necessary to develop such information.

The petitioners do not demonstrate "testing of such substance or mixture with respect to such effects is necessary to develop such information." EPA finds that the petitioners failed to address ongoing testing and data collections for some of the 54 PFAS, thereby failing to set forth

facts that are necessary to establish there is a need for the testing sought in the petition. This research may provide information that overlaps with testing the petitioners requested, which would render the information unnecessary under TSCA section 4(a)(1)(A)(i)(III). Testing, both planned and underway, on some of the 54 PFAS that the petitioners identify is described in this unit:

• Five of the 54 PFAS have been subjected to all Tier 1 in vitro, toxicokinetic, and clearance studies: hepatotoxicity, developmental toxicity, immunotoxicity, mitochondrial toxicity, developmental neurotoxicity, endocrine disruption, general toxicity, intrinsic hepatic clearance, plasma protein binding (PPB), and renal reuptake. These studies are ongoing and results are expected by April 2021. Data are expected to be available via the PFAS Dashboard by the end of June 2021.

• An additional six of the 54 PFAS have results from some Tier 1 in vitro testing. Two have been included in systematic evidence mapping (SEM), a systematic review approach used to identify available data and characterize knowledge gaps.

• Three of the 54 PFAS have in vivo data identified from a non-EPA source.

In addition, the following studies are planned or in process by EPA's Office of Research and Development (ORD).

• ORD will test for nuclear receptor and stress gene responses of a PFAS library in HepG2 cells. This research will apply a high-throughput assay for transcription factor activation to screening the first and second PFAS screening sets totaling 150 samples. Additional samples may be added to meet developing needs. This assay platform contains known targets of several PFAS including the estrogen receptor and peroxisome proliferator-activator receptors, as well as many other potential targets. Well-studied PFAS such as PFOA and PFOS will be included to

help put findings for data-poor chemicals in better context. Data sets will support development of read-across and category approaches for this class of chemicals.

• Bioactivity of PFAS as determined using gene expression and in vitro cellular pathology is another area of ongoing research at EPA. This research will apply broad-based high-content screening assays to characterize the bioactivity of a set of PFAS in multiple human cell types. The resulting dataset will contribute to an overall assessment of the effects of PFAS on important physiological functions that overlap with effects measured in the testing the petitioners requested.

• ORD will also conduct high-throughput in vitro testing of PFAS to fill data gaps and refine structural and mechanistic groupings. This project falls under the Human Health Testing/Toxicokinetics research area that will generate and analyze a large data set on ~150 PFAS using a variety of New Approach Methodologies (NAMs) in support of EPA's mission to manage and regulate PFAS. This research effort will add a dataset of NAMs testing results for 15 PFAS. Selection of these 15 chemicals will be driven by the initial analysis of the 150 chemicals and provide the ability to fill identified data gaps and potentially test hypotheses developed from the initial analysis. Testing of these 15 PFAS will include transcription factor activity profiling; estrogen-dependent cell proliferation; high-content, cellular phenotypic imaging; high-throughput transcriptomics; zebrafish embryo development; and developmental neurotoxicity. The results will support the overarching EPA PFAS research to: (1) Develop a hierarchical scheme of chemical structural categories that are enriched by NAM data; (2) Use categories as predefined neighborhoods to evaluate degree of concordance in NAM results within categories and across categories as a means to infer in vivo toxicity; (3) Predict categorization of larger PFAS inventory and read-across coverage; and (4) Recommend further in vivo testing for PFAS

categories.

• In the FY2020 Further Consolidated Appropriations Act (P.L. 116-94), Congress appropriated funds for EPA to address research needs in support of designating PFAS as hazardous substances under CERCLA. The research needed to help support this designation include: Chemical and physical characteristics of PFAS; Toxicity and kinetic information; environmental prevalence; Manufacturing and use information; and Information on the regulatory status of PFAS. This ongoing research will add significantly to currently available hazard information for PFAS that could be used for this designation, as well as for risk assessment use broadly by Program Offices.

NDAA section 7351 amended TSCA section 8(a) to include a one-time reporting event of PFAS manufactured (including imported) in any year since January 1, 2011. TSCA section 8(a)(7) authorizes EPA to collect "[a]ll existing information concerning the environmental and health effects of such substance or mixture." Under this rule, EPA may collect information that overlaps with some of the information requested by petitioners. A final TSCA section 8(a) rule for these PFAS must be issued by January 1, 2023, and EPA has initiated the relevant rulemaking process for the proposed rule that is expected to be issued in 2021.

The petitioners also call for an epidemiologic study consisting of 100,000 participants from communities exposed to PFAS-contaminated drinking water. A similar, multi-site health study is being implemented through the Centers for Disease Control and Prevention and ATSDR cooperative agreements. As ATSDR states, "[i]nformation learned from the multi-site study will help all communities in the U.S. with PFAS exposures, including those that were not part of the study." The petitioners mention this multi-site study but provide no analysis of overlap or what testing might be duplicative with what is proposed and thus might not be necessary, whether

based on community characteristics, demographics, specific PFAS or mixture, or levels of exposure.

For some of the 54 PFAS, only a degradant is detected in the Cape Fear River per the information provided by petitioners, not the parent chemical for which the petitioners have requested testing. The petitioners have not identified why it is necessary to test the parent chemicals and not the degradants actually detected in the Cape Fear River. For example, the petitioners do not demonstrate that testing of the parent chemical would identify effects relevant to the degradants.

The petitioners specifically identify and acknowledge that "5 of the 54 listed chemicals in this petition are also designated for testing in the Chemours North Carolina consent decree. These tests would not need to be replicated in response to this petition" (Ref. 1, pg. 30). EPA finds this avoidance of duplicative testing tacitly acknowledges that for these five PFAS, testing is not necessary to develop information on health or environmental effects. The petitioners' attempt to avoid duplicative testing as a result of the Chemours North Carolina consent decree, but no other duplicative testing, further emphasizes their failure to address readily available information concerning the other activities EPA has identified in this unit.

3. Class-based approach to testing.

TSCA section 4(h)(1)(B)(ii) "encourage[s]" EPA to consider "the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide scientifically valid and useful information on other chemical substances in the category." Accordingly, EPA is currently investigating ways to group similar PFAS by likeness into subcategories for purposes of research, data collection, hazard determinations, and other activities (Ref. 18). EPA and the National Toxicology Program

collaborated to construct a PFAS screening library subset composed of 75 PFAS on a structural category basis and considerations such as structural diversity within a category, data availability, and read-across category-level weight (e.g., value of substance for anchoring read-across trends within a category, serving as an analog); four of the 54 PFAS the petitioners identify are included in this subset (Ref. 19). The petitioners mention this effort, but incorrectly state that just two of the 54 PFAS the petitioners cover are included in the EPA testing (Ref. 1, pg. 22).

The petitioners take the opposite approach, requesting testing on each of the 54 PFAS individually. The petitioners fail to address why a class-based approach is not appropriate, while also indirectly referring to the efforts to address PFAS as a class. For example, the petitioners allege that conclusions about all 54 PFAS can be based on the ATSDR 2018 Toxicological Profile even though none of the 54 PFAS are addressed in the toxicological profile, and concedes that the ATSDR 2018 Toxicological Profile "identifies numerous critical data gaps for PFAS ***as a class***" (emphasis added). Additionally, among the references allegedly supporting the assertion that PFAS present serious health and environmental concerns, the petitioners cite a commentary entitled "Scientific Basis for Managing PFAS as a Chemical Class" (Ref. 20). This commentary acknowledges PFAS "demand a more efficient and effective approach" when it comes to testing and seeks to "provide scientific justification for why a class-based approach is appropriate and necessary for all PFAS." Because the petitioners acknowledge the 54 PFAS share similarities with other members of the class, and the petitioners do not explore these similarities as a means of streamlining the extent of the testing requested, or to inform the petitioners' "tiered screening and testing process," EPA finds the petitioners have not provided the facts necessary to determine, for each of the 54 PFAS, that "testing of such substance or mixture with respect to such effects is necessary to develop such information." Therefore, they have not demonstrated

that the rule or order they requested is necessary.

4. Practicability of National Academy of Sciences oversight.

The petitioners also request that the National Academy of Sciences (NAS) oversee all aspects of the proposed testing program. EPA finds such an oversight arrangement is not within the scope of what a TSCA section 21 petitioner can request when seeking the initiation of a rule or the issuance of an order under TSCA section 4. Further, projects and studies must meet certain conditions for the NAS to accept private funding. As an example, NAS does not generally oversee studies where the study sponsor would have a direct financial interest in the outcome of the testing program. EPA is not in a position to require NAS to oversee the testing requested by the petitioners, and the petitioners provide no administrative or organizational procedures for implementation.

5. Selection of PFAS for health and environmental effects testing.

Attachment 2 of the petition divides the 54 PFAS at issue into Tier 1 substances "for which there is known human exposure based on detection in blood, food or drinking water," and Tier 2 substances "for which human exposure is probable based on detection in environmental media." However, the petitioners do not set forth facts showing that for all 40 PFAS it ranks as Tier 2 substances, "human exposure is probable based on detection in environmental media" or that "a strong inference of exposure can be drawn from their presence in surface water, stormwater, wastewater, sediment, groundwater, soil, private wells, and/or air emissions" (Ref. 1, pg. 19). The petitioners support their assertion that some of the Tier 2 PFAS were detected in environmental media with two studies (Ref. 21, 22); for nine of these, no other studies are provided for inclusion based on presence in environmental media (Ref. 1, Attachment 2). Three of these nine PFAS were not directly detected in the two studies. Further, for some of these nine

PFAS, only degradant products were detected in the Cape Fear River; the parent compounds the petitioners specifically identify for testing were not. Thus, for nine of the 54 PFAS, the petitioners provide weak or no evidence for presence in environmental media upon which to base its "strong inference of exposure" assertion (Ref. 1, pg. 19).

6. Scientific standards.

EPA finds the petitioners have not evaluated the quality of the data they have provided or indicated how they conducted their searches, evaluated the quality of the sources, or indicated what gaps were located and then explained why the specific tests requested, as compared to others, would provide the data being sought. Such an evaluation is necessary for EPA to conduct the considerations under TSCA section 26(h).

7. Vertebrate testing.

TSCA section 4(h) requires that EPA reduce and replace the use of vertebrate animals in the testing of chemical substances under TSCA section 4. EPA must consider "as appropriate and to the extent practicable and scientifically justified, reasonably available existing information, including (i) Toxicity information; (ii) Computational toxicology and bioinformatics; and (iii) High-throughput screening methods and the prediction models of those methods."

The testing program the petitioners request would require testing on vertebrates. For example, OCSPP Test Guidelines 850.2300, 870.3650, and 870.7800, among other test guidelines, require vertebrate testing. Due to the number of PFAS involved and tests requested, the petitioners' request would require testing on a large number of vertebrates. Yet, as previously discussed, the petition fails to provide reasonably available existing toxicity information on the 54 PFAS, and as such the petition has not provided sufficient facts for EPA to consider

reasonably available existing information and encourage and facilitate the use of test methods that reduce or replace the use of vertebrates, group chemical substances as appropriate to reduce the use of vertebrates, and facilitate the formation of consortia for jointly conducted testing.

C. What was EPA's Conclusions?

EPA denied the request to initiate a rule or issue an order under TSCA section 4 because the TSCA section 21 petition does not set forth the facts necessary for the Agency to determine for each of the 54 PFAS that existing information and experience are insufficient and testing of such substance or mixture with respect to such effects is necessary to develop such information. Therefore, the petitioners have not demonstrated that the rule or order they requested is necessary.

V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. Center for Environmental Health, Cape Fear River Watch, Clean Cape Fear, Democracy Green, Toxic Free NC, The NC Black Alliance to Andrew Wheeler, Administrator, Environmental Protection Agency. Petition to Require Health and Environmental Testing Under the Toxic Substances Control Act on Certain PFAS Manufactured by Chemours in Fayetteville, North Carolina. October 13, 2020.

2. Agency for Toxic Substances and Disease Registry (ATSDR). Notice; Availability of

Draft Toxicological Profile: Perfluoroalkyls. ***Federal Register.*** 83 FR 28849, June 21, 2018 (Docket No. ATSDR-2015-0004).

3. EPA. EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan. EPA 823R18004. February 14, 2019. *https://www.epa.gov/pfas/epas-pfas-action-plan.*

4. EPA. Proposed Rule; Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule. ***Federal Register.*** 80 FR 2885, January 21, 2015 (FRL-9915-63).

5. EPA. Consent Order regarding DuPont Premanufacture Notices P08-508 and P09-509. (2009). *https://chemview.epa.gov/chemview/proxy?filename=sanitized_consent_order_p_08_0508c.pdf.*

6. EPA. Notice of Availability; Lifetime Health Advisories and Health Effects Support Documents for Perfluorooctanoic Acid and Perfluorooctane Sulfonate. ***Federal Register.*** 81 FR 33250, May 25, 2016 (FRL-9946-91-OW).

7. EPA. Fact Sheet: 2010/2015 PFOA Stewardship Program. Washington, DC: US Environmental Protection Agency, Office of Pollution Prevention and Toxics. *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-20102015-pfoa-stewardship-program*.

8. EPA. Final Rule; Perfluoroalkyl Sulfonates; Significant New Use Rule. ***Federal Register.*** 67 FR 11008, March 11, 2002 (FRL-6823-6).

9. EPA. Final Rule; Perfluoroalkyl Sulfonates; Significant New Use Rule. ***Federal Register.*** 67 FR 72854, December 9, 2002 (FRL-7279-1).

10. EPA. Final Rule; Perfluoroalkyl Sulfonates; Significant New Use Rule. ***Federal Register.*** 72 FR 57222, October 9, 2007 (FRL-8150-4).

11. EPA. Final Rule; Perfluoroalkyl Sulfonates and Long-Chain Perfluoroalkyl Carboxylate Chemical Substances; Final Significant New Use Rule. ***Federal Register.*** 78 FR 62443, October 22, 2013 (FRL-9397-1).

12. EPA. Final Rule; Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule. ***Federal Register.*** 85 FR 45109, July 27, 2020 (FRL-10010-44).

13. EPA. Draft Compliance Guide for Imported Articles Containing Surface Coatings Subject to the Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances Significant New Use Rule; Notice of Availability and Request for Comment. ***Federal Register.*** 85 FR 81466, December 16, 2020 (FRL-10017-86).

14. EPA. Final Rule; Fluoroalkenes; Final Test Rule. ***Federal Register.*** 52 FR 21516, June 8, 1987 (FRL-3214-8).

15. Williams, A.J., Grulke, C.M., Edwards, J. et al. The CompTox Chemistry Dashboard: a community data resource for environmental chemistry. *Journal of Cheminformatics.* 9**,** 61. 2017.

16. EPA. Introduction to ChemView. May 28, 2020. *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/introduction-chemview.*

17. DuPont Haskell Global Centers to 8(e) Coordinator, Office of Pollution Prevention and Toxics, Environmental Protection Agency. Substantial Risk Report for 3,3,3-Trifluoromethyl-1,2,2-trifluorovinyl ether, CAS #1187-93-5. November 8, 2007. *https://chemview.epa.gov/chemview/proxy?filename=2007-11-8EHQ-07-16360B_8ehq_1107_16360b.pdf.*

18. EPA. EPA and Partners Describe a Chemical Category Prioritization Approach to

Select 75 PFAS for Testing using New Approach Methods. February 26, 2019. *https://www.epa.gov/sciencematters/epa-and-partners-describe-chemical-category-prioritization-approach-select-75-pfas.*

19. Patlewicz, G. et al. A Chemical Category-Based Prioritization Approach for Selecting 75 Per- and Polyfluoroalkyl Substances (PFAS) for Tier Toxicity and Toxicokinetic Testing. *Environmental Health Perspectives* 127(1). January 11, 2019. *https://doi.org/10.1289/EHP4555*.

20. Kwiatkowski, C. et al. Scientific Basis for Managing PFAS as a Chemical Class. *Environmental Science & Technology Letters*. 7,8:532-543. 2020. *https://doi.org/10.1021/acs.estlett.0c00255*.

21. Strynar, M. et al. Identification of Novel Perfluoroalkyl Ether Carboxylic Acids (PFECAs) and Sulfonic Acids (PFESAs) in Natural Waters Using Accurate Mass Time-of-Flight Mass Spectrometry (TOFMS). *Environmental Science & Technology*. 49: 11622-116302015. *https://pubs.acs.org/doi/abs/10.1021/acs.est.5b01215*

22. McCord, J. and M. Strynar. Identification of Per- and Polyfluoroalkyl Substances in the Cape Fear River by High Resolution Mass Spectrometry and Nontargeted Screening. *Environmental Science & Technology* 53(9): 4717-4727. 2019. *https://doi.org/10.1186/s13321-017-0247-6*.

Authority: 15 U.S.C. 2601 *et seq*.

Dated: January 7, 2021.

Alexandra Dapolito Dunn,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.